EADSI
East African Drug Seller Initiative

East Africa Drug Seller Initiative (EADSI)
Evaluation Report

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TABLE OF CONTENTS

I.   Executive Summary

Funded by the Bill & Melinda Gates Foundation through a three-year grant, The East African Drug Sellers Initiative (EADSI) built on successes of Management Sciences for Health's (MSH) Strategies for Enhancing Access to Medicines (SEAM) Program. In collaboration with the government of Tanzania, SEAM launched the country's successful accredited drug dispensing outlet (ADDO) program. One of EADSI's objectives was to strengthen the ADDO model in Tanzania to facilitate scale-up and sustainability. Another EADSI objective was to develop a plan to replicate the ADDO model to scale in Uganda and demonstrate the adapted model in one district. The newly accredited and improved shops in Uganda's Kibaale district were named Accredited Drug Shops (ADS).

Summaries of the implementation activities in Tanzania and Uganda are in Annex 1.

In line with EADSI's goal of creating a sustainable model to replicate and scale-up private-sector drug seller initiatives in developing countries, the monitoring and evaluation framework centered on three dimensions—scalability,[1] sustainability,[2] and transferability.[3] To guide the evaluation process, an evaluation framework clearly spelled out the intervention dimensions, variables/expected outcomes, specific indicators, and the methodology for collecting the required indicators. The evaluation combined a number of data collection approaches, including price and availability surveys within drug outlets, mystery shopping to evaluate drug seller practices, and household surveys to assess user perceptions on various aspects of the program and disease burden. We also collected qualitative data on stakeholders' perspectives of the programs in Tanzania and Uganda. Additional data on institutionalization, legal and regulatory framework, and operational funding were collected through review of government documents on implementation and operations.

In Tanzania, we carried out the scalability evaluation in the intervention region of Singida, where the ADDO program was being scaled up under a decentralized model, and compared it with the control region of Mara, which still had unaccredited shops in operation. Ruvuma and Mtwara regions were used to evaluate the sustainability aspects of the ADDO program because Ruvuma was the first region to pilot the initiative and Mtwara was one of the first regions to scale-up the ADDO program. For transferability, we selected Uganda, with Kibaale as the intervention district and Mpigi as the comparison district.

In assessing scalability, we evaluated the decentralized ADDO implementation model, which shifted implementation to the districts from the central level and allowed for multiple regions to be scaled up simultaneously with TFDA oversight. The revised model was proven to be successful; for example, while it took Tanzania 6 years to roll out the ADDO program in 4 regions using the original centralized implementation model, 10 more regions completed implementation within 3 years using the new decentralized approach without sacrificing accessibility. In addition, the revised implementation model resulted in significant reduction in rollout costs per district; TFDA estimated that the savings were greater than 50%.

In relation to the quality of dispensing services using the decentralized model, the mystery shopper exercise in Tanzania showed that Singida (the pilot district) demonstrated significant improvements in the quality of dispensing for both malaria and diarrhea compared to Mara. For the uncomplicated malaria case scenario, dispensers in Singida improved against all indicators, such as asking about symptoms. Case management of non-bloody diarrhea also improved in Singida; for example, the dispensing of antibiotics for non-bloody diarrhea decreased by 23% (98% baseline to 76% at end line) while in Mara, it remained relatively unchanged (84% baseline to 87% endline). The use of oral rehydration solution increased from 20% to 33% in Singida, while Mara recorded a marginal difference pre and post intervention.

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[1] Defined as the ability to expand an intervention to support larger system without affecting performance
[2] Defined as persistence of the intervention's effect over time
[3] Defined as extent to which an intervention can be replicated and implemented in a new country

Although promising, some of these results are not statistically significant, and certain practices still fall short. Case management of simple malaria was unchanged in Singida before and after the intervention, which may have been related to the fact that Tanzania was experiencing nationwide shortages of the recommended first-line treatment during the intervention. So, although dispensers were trained to dispense the recommended artemether-lumefantrine, it was not available for them to dispense.

Sustainability was demonstrated in assessments of two of the regions which were early implementers of the ADDO initiative. For the longest-running region, Ruvuma, all of the shops surveyed in 2010 reported making profits, and compared to 2004, the amount of profit had increased. Also in Ruvuma, we compared the indicators across an eight-year span to measure how well the ADDOs were maintaining the quality of services: 2002 which was pre-implementation; 2004, which was post-implementation; and 2010, after the accredited shops had been operating for up to seven years. In general, the quality of pharmaceutical services delivered by ADDO dispensers in Ruvuma was maintained and for some indicators, even improved. The percentage of encounters where the customer received malaria treatment according to standard treatment guidelines has risen dramatically since the post-implementation evaluation (6% in 2002; 24% in 2004; 63% in 2010). Considering that dispensers in Ruvuma received little continuing education or regular supportive supervision since the original pilot in 2003, the results are notable.

Transferability was demonstrated in Uganda. By the end of the EADSI program, 73 Class C drug shops were accredited to operate as ADS, and 246 drug sellers and 82 owners were trained in proper dispensing and business skills. Although all dispensing service indicators, such as asking if the child was taking other medicines, improved in the ADS district of Kibaale, none of the improvements were statistically significant. The percentage of encounters with appropriate dispensing for simple malaria in Kibaale rose from 6% to 68% following the intervention. Some of the important findings in Kibaale related to decreases, rather than increases; for example, the availability of the recommended first-line antimalarial medicine for uncomplicated malaria, artemether-lumefantrine, increased in both the intervention district and control district. These increases could have been affected by other concurrent interventions. However, a dramatic fall in the availability of antimalarials that are not recommended for first-line treatment, chloroquine (80% to 2%) and sulfadoxine-pyrimethamine (88% to 7%), in Kibaale, but not in Mpigi, appears to be a result of the EADSI intervention. In addition, the availability of injectables in ADS fell to 0 compared with 61% at baseline, while the availability in Mpigi did not change. Injectables are not allowed to be sold by either Class C shops or ADS.

Interviews with ADS stakeholders showed general satisfaction with the accreditation concept and the implementation process. The main reason that owners cited for participating in the initiative was the expanded list of allowable drugs for sale. The 64 shop owners and sellers who were interviewed post-intervention also appreciated inspectors' visits, saying that they "*give us advice that is helpful to the business*." This was a changed attitude from before to the intervention: "*I don't mind NDA or district inspectors, NDA used to be very hostile to us; it's now like eating on the same plate with a lion. They are all very supportive*"—ADS owner from Kagadi.

II.   Background

The goal of EADSI was to create a sustainable accredited drug seller model that can be adapted, replicated, and scaled up in underserved regions of developing countries and that will ultimately operate independent of donor support. EADSI built on successes of MSH's SEAM Program,[4] also funded by the Gates Foundation. In collaboration with the government of Tanzania, SEAM launched the country's successful ADDO program.

One of EADSI's objectives was to strengthen the ADDO model in Tanzania to facilitate scale-up and sustainability. Crucial to SEAM's success in Tanzania was building stakeholder relationships in every part of the ADDO initiative and ensuring that a Tanzanian organization "owned" and controlled the initiative. To revise the ADDO model in Tanzania, EADSI used the same approach and reached out to Tanzanian stakeholders to help identify necessary changes to the ADDO model that would help ensure successful scale-up and financial sustainability. Therefore, to achieve this objective, the program conducted stakeholder workshops to review the ADDO experiences of SEAM and the Rational Pharmaceutical Management Plus Program,[5] as well as the scale-up experiences of the Tanzania Food and Drugs Authority (TFDA).[6] To investigate ways to assure financial sustainability, the review determined ADDO owners' and dispensers' cost contributions to the program, other potential sources of financing, and possible ways to increase efficiencies. Based on stakeholder recommendations, EADSI and its partners reviewed and revised the Tanzanian national ADDO rollout and maintenance strategy and associated budgets. The revised strategy served as the basis for the creation of a plan that defines what a sustainable initiative requires and that addresses maintenance issues such as re-accreditation and continuing education for dispensers.

Another EADSI objective was to develop a plan to replicate the ADDO model to scale in a second East African country and demonstrate the adapted model in one district. Uganda was selected for this objective. Class C drug shops are licensed by Uganda's National Drug Authority (NDA) to sell over-the-counter drug products. However, most also illegally sell prescription drugs, such as antibiotics, and many drug sellers also provide injection services. Although over 40% of the 106 drug sellers interviewed in an EADSI assessment in 2008 refused to answer a question about sales of prescription medicines, about 28% of those who responded said they were unaware of the medicines that they were not allowed to stock. At the start of this project, NDA had licensed over 4,000 Class C drug shops nationwide, but thousands more were estimated to be operating without licenses. Most shops do not use signage to identify themselves as drug sellers, which allows them to evade NDA inspectors more easily.

To increase access and improve practices, the EADSI Program worked with Ugandan national and local stakeholders to develop an accreditation model based on Tanzania's ADDO initiative, but adapted to the Ugandan context. NDA, in collaboration with the Pharmaceutical Society of Uganda and MSH, selected two districts, Kibaale and Mpigi, to serve as the demonstration and control districts for the new initiative. The newly accredited and improved shops were named Accredited Drug Shops.

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[4] SEAM website: http://www.msh.org/SEAM/

[5] Ministry of Health and Social Welfare/Tanzania Food and Drugs Authority. *Report on Stakeholder's Meeting on Reviewing and Revising the Tanzania ADDO Model*. St Gaspar Hotel & Conference Centre, Dodoma, Tanzania. July 5, 2008.

[6] Ministry of Health and Social Welfare/Tanzania Food and Drugs Authority. *The 2nd ADDO Stakeholders Meeting Report: Reviewing the Tanzania ADDO Model and Assessing Progress on Implementation of the Recommendations of the 1st Stakeholders Meeting*. Morogoro Hotel 8th-10th September 2009.

The specific objectives in developing Uganda's ADS model were to—

- Increase access to quality essential medicines, particularly in remote areas, through private sector drug sellers
- Strengthen the regulatory monitoring and inspection of drug sellers by national and local authorities
- Improve the quality of drug shop dispensing services through training, accreditation, supervision, and continuing education
- Improve the record keeping practices for medicines sold, including purchases, adverse drug reactions, referrals, and financial and sales records
- Increase drug shop sustainability through business skills training for owners and access to loans to improve premises and expand inventory
- Raise consumer awareness of the need to buy medicines from reliable sources, such as accredited drug sellers

Specific activities included development and NDA approval of ADS standards that focused on personnel, premises, dispensing, record keeping, and a code of ethics for owners and sellers. Stakeholders also collaborated to develop training curricula for drug sellers and shop owners, a list of prescription medicines that ADS could sell legally, guidelines for a supportive supervision and inspection system, and a marketing campaign. Implementation activities included conducting local sensitization meetings, mapping and inspecting the existing licensed and unlicensed drug shops, and training 246 sellers in dispensing and 82 owners in business practices. In addition, local monitoring and supervising teams received training in accreditation standards and how to use checklists. After a local media campaign to raise awareness, the ADS program was officially launched by the Minister of Health in November 2009 with a community celebration.

III. Program Evaluation

In line with EADSI's goal of creating a sustainable model to replicate and scale-up private-sector drug seller initiatives in developing countries, the monitoring and evaluation (M&E) framework centered on three dimensions—scalability,[7] sustainability,[8] and transferability.[9] Because the sustainability of a private sector-based program leans heavily on economic viability, the evaluation also included a business component. Sustainability indicators also measured accessibility to essential medicines and dispensing services over time, including access to quality services, impact on prices, and the availability of essential medicines. Evaluation of scalability focused on the decentralized implementation model and whether the revised model continued to support improved accessibility. Evaluation of transferability focused on the experience in replicating the model in Uganda.

For the **scalability** component, the evaluation sought to address the following key questions—

- Is the decentralized ADDO implementation model effective in scaling up the ADDO program? (Singida vs. Mara)
    - Availability of pharmaceutical products
    - Quality of dispensing services
    - Price change for drugs following ADDO implementation
- Is the decentralized approach cost-effective and were stakeholders satisfied with it? (Singida vs. Mtwara)
- What broader efforts will help ensure scalability?
    - Local inspection systems
    - Institutionalization of ADDOs

For the **sustainability** component, the evaluation sought to address the following key questions—

- Can the ADDO program improvements be sustained beyond one year? (Ruvuma and Mtwara)
    - Availability of pharmaceutical products
    - Quality of dispensing services
    - Price change for drugs following ADDO implementation
- Are ADDOs profitable (Ruvuma and Mtwara)?
- Do ADDOs satisfy community needs over time? (Ruvuma, Mtwara, and Singida)

For the **transferability** component, the evaluation sought to address issues relating to the adaptation and transfer of the ADDO program to Uganda. Specifically, this component sought to address the following questions—

- Was Tanzania's ADDO model effectively adapted and replicated for Ugandan context and needs?
    - Availability of pharmaceutical products?
    - Quality of dispensing services?
    - Price change for drugs following ADS implementation?
- Did key stakeholders express satisfaction with the pilot/demonstration of ADS intervention in the Kibaale district?
- Do ADS satisfy community needs?

Cross-cutting components in the M&E framework were based on the SEAM access framework, which was a collaborative effort with the World Health Organization (WHO) and other pharmaceutical and assessment experts to define and

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measure access to medicines.[10] The SEAM access framework defines four dimensions of access as: *availability*, *affordability* (a combination of product price and ability to pay), *geographic accessibility*, and *acceptability* (or satisfaction). In addition, the quality of products and services was defined as an essential component that cuts across all dimensions of the access framework. In the EADSI evaluation, we included service quality, product price (but not ability to pay), and product availability. In addition, we captured data related to consumers' and shop owners' acceptability and satisfaction through household surveys and interviews. Consumer satisfaction is a challenging dimension to measure. In the SEAM evaluation, we conducted interviews with customers as they left drug outlets and asked them how they felt about the service quality. We found that no one was willing to say anything negative (probably a cultural phenomenon), so the results were questionable. In this evaluation, we wanted to characterize illness and care seeking behavior in the community and determine people's preferences regarding buying drugs.

Evaluation methodology

To guide the evaluation process, an evaluation framework was developed (Annex 2). The framework clearly spelled out the intervention dimensions, variables/expected outcomes, specific indicators, and the methodology for collecting the required indicators. The evaluation combined a number of approaches including desktop reviews, price and availability surveys within drug outlets, mystery shopping to evaluate drug seller practices, and household surveys to assess user perceptions on various aspects of the program and disease burden.

Setting

In Tanzania, we carried out the evaluation in Singida (intervention region), where the ADDO program was being scaled up under a decentralized model, and compared it with Mara (control region), which still had unaccredited shops, *duka la dawa baridi* (DLDB), in operation. We selected the two regions because they are comparable in several health and socioeconomic indicators.[11] Ruvuma and Mtwara regions were used to evaluate the sustainability aspects of the ADDO program because Ruvuma was the first region to pilot the initiative and Mtwara was one of the first regions to scale-up the ADDO program. In Uganda, we selected Kibaale as the intervention district and Mpigi as the comparison district. As in Tanzania, the two districts had similar demographic indicators.

Survey and data collection

For the price and availability survey to determine accessibility (part of scalability, sustainability, and transferability), we collected data on pharmaceutical product price and product availability on 30 tracer drugs using data collection tools that were based on SEAM and WHO/Health Action International methodologies[12]. The list of drugs selected as tracers in each country are shown in Annex 3. Thirty randomly selected drug shops in each study area (Singida, Mara, Ruvuma, and Mtwara regions in Tanzania and Kibaale and Mpigi districts in Uganda) were included in the price and availability survey. To randomly select the shops in Tanzania, we used the map of each study area that listed drug shops, numbered the shops on the list, and chose every fifth one. Because Uganda's districts are smaller, we included all mapped shops in the list to visit in Kibaale and Mpigi.

For assessing accessibility of quality pharmaceutical services (scalability, sustainability, and transferability), we used mystery shoppers to simulate either cases of a child with uncomplicated malaria or a child with non-bloody diarrhea. The mystery shoppers received guidance on how to present the cases prior to the visits (Annex 4). To reduce suspicion among shop attendants, shops that had been visited for the price and availability survey were not included in the

[10] Center for Pharmaceutical Management. 2003. *Defining and Measuring Access to Essential Drugs, Vaccines, and Health Commodities: Report of the WHO-MSH Consultative Meeting, Ferney-Voltaire, France, December 11–13, 2000.* Prepared for the Strategies for Enhancing Access to Medicines Program. Arlington, VA: Management Sciences for Health. http://www.msh.org/seam/reports/Access_Meeting_Ferney_Voltaire_1.pdf

[11] National Bureau of Statistics (NBS) [Tanzania] and ICF Macro. 2011. Tanzania Demographic and Health Survey 2010. Dar es Salaam, Tanzania: NBS and ICF Macro. http://www.nbs.go.tz/pdf/2010TDHS.pdf

[12] WHO/HAI Tool Kit: http://www.who.int/entity/medicines/.../training_slides_data_collection.pdf

mystery shopping exercise. Sixty shops were randomly selected for each disease scenario in Tanzania's Singida, Mara, and Ruvuma regions (120 shops per region total). However, due to logistics problems, shop closures, and refusals, we actually visited fewer shops than planned (Table 1). A similar mystery shopping exercise was conducted in Kibaale and Mpigi districts in Uganda. Because the exercise was conducted in Ugandan districts, which are much smaller areas than Tanzanian regions, the total numbers of drug shops included in the mystery shopping exercise were even smaller (Table 1). Because of this limitation, we only used the uncomplicated malaria scenario in Uganda.

Table 1: Sample Sizes for EADSI Evaluation

Region/District	Baseline			Endline			
	Product availability and price survey (shops)	Quality of services and appropriateness of dispensing (shops)	Household survey (house-holds)	Product availability and price survey (shops)	Quality of services and appropriateness of dispensing (shops)	Household survey (house-holds)	Financial assessment (shops)
Singida	32	41	308	29	61	290	29
Mara	33	45	333	32	58	328	N/A
Kibaale	66	16	295	45	19	299	N/A
Mpigi	64	20	300	41	19	300	N/A
Ruvuma	No baseline data available			29	31	301	61
Mtwara	No baseline data available			31			54

N/A = not applicable

To evaluate consumer satisfaction with services provided by drug shops and to assess if drug shops met community needs (disease burden), we designed and conducted a household survey based on WHO methodology[13] in Singida, Mara, and Ruvuma regions in Tanzania and Kibaale and Mpigi districts in Uganda. We surveyed 300 households in each region/district. We randomly chose households surrounding the 30 randomly chosen shops used in the price/availability data collection exercise. We visited the first 10 households met by walking in a straight line from the shop.

For the sustainability component, we collected data on product availability and prices and ADDO profitability from the shops that are still operational since inception in Ruvuma and Mtwara.

To assess transferability (Uganda) and some aspects of scalability and sustainability (Tanzania), we collected qualitative data on stakeholders' perspectives of the program. Interviews were conducted with ADDO and ADS owners, ADDO dispensers and ADS sellers, and local and central government authorities. Additional data on institutionalization, legal and regulatory framework, and operational funding were collected through review of government, TFDA, and NDA documents on implementation and operations.

Data analysis

Data were entered into an Excel program to generate frequencies and central tendencies. Further statistical analyses were conducted using SPSS for Windows version 18. We analyzed the difference between intervention and control areas on variables related to availability of medicines and dispenser practices. The McNemar's test was used to perform within group comparisons, while the Chi-squared goodness of fit test was used to test between group differences following the intervention.

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[13] Ibid.

Ethical considerations

TFDA and NDA provided authorization to conduct the evaluations. Drug shop owners and sellers as well as heads of household agreed to take part in interviews after being briefed on the project. The data collectors verbally assured participants of their anonymity, the confidentiality of information collected, and freedom to withdraw consent at any time during the process. Additionally, prior to data collection, we held meetings with district officials and ward and village leaders in the study communities to seek their approval and ask them to disseminate information about the study to their communities. At the end of the project, we invited select district-level officials and drug shop owners and dispensers in workshops to discuss preliminary study findings.

IV.   Results Related to Scalability (Tanzania)

Did ADDOs increase the availability of products in Singida compared to Mara?

To assess the effect of the ADDO intervention on product availability, we categorized the tracer drugs into Part I and Part II drugs. Part I drugs are legally designated to be sold as prescription only in registered pharmacies, while Part II drugs, often referred to as over-the-counter medicines, are legally permitted to be sold in both drug shops (DLDBs and ADDOs) and pharmacies without a prescription. As part of the ADDO program, TFDA regulations specifically allow ADDOs to sell a limited list of certain Part I medicines, such as antibiotics. All Part I items on the tracer list were approved for sale in ADDOs, but not in DLDBs. As a result, one would expect an increase in Part I drugs in ADDOs in Singida and no change in Mara over time. Any Part I sales at baseline in either region would have been illegal sales, as would any Part I sales at endline by DLDBs in the control region, Mara.

Annex 5 includes the availability results on the full list of tracer drugs classified by Part I and Part II medicines.

Availability of Part I (prescription only) vs. Part II (non-prescription) medicines

Table 2 compares the availability of each tracer item in regions before and after the program. We averaged the availability of each medicine in each category across the shops, and then created an average for the category. As expected, the results show a larger increase in product availability in Singida compared to Mara for Part I drugs (Figure 2a). However, the evaluation occurred as the ADDO program was scaling-up nationwide with ongoing sensitization programs. This attention could have contributed to the marginal increases observed in Mara.

Figure 2a. Average availability of Part I medicines
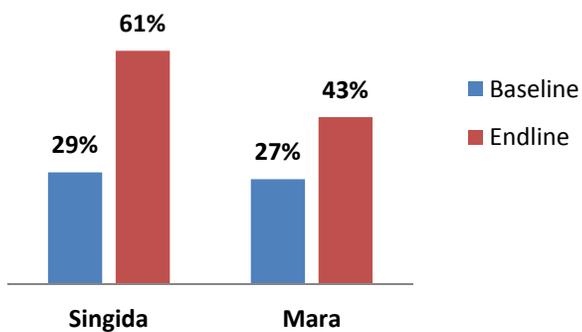
Figure 2b. Average availability of Part II medicines
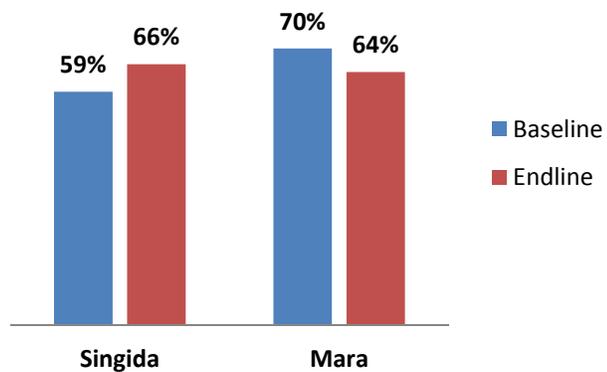
Availability of antimalarial medicines

At the time of the intervention, the recommended first-line treatment for uncomplicated malaria in Tanzania was artemether-lumefantrine (AL). However, regulations prohibited this product from being stocked in DLDBs. Following the intervention, ADDOs were allowed to stock the product. At the time of this evaluation, however, no statistically significant increase was seen in AL in Singida, perhaps because of price-related issues and because a nationwide supply problem prevented AL from being widely available. The most readily available and least expensive antimalarial product on the market was sulfadoxine-pyrimethamine (SP). The availability of SP increased from 66% to 83% following the intervention in Singida. Figures 3a and 3b show the availability of AL and SP in the intervention and control regions before and after ADDO scale-up in Singida. Chloroquine was not available in either region at baseline and endline. Table 2 shows full availability data on antimalarials.

Figure 3a. Percent of shops with artemether-lumefantrine 20/120 mg 6x4 tablets
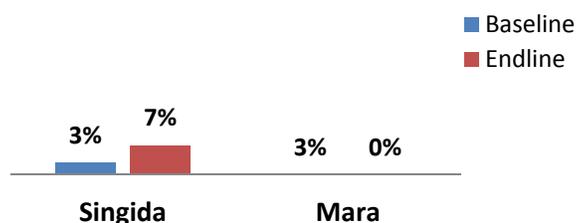
Figure 3b. Percent of shops with SP 500/25 mg tablets
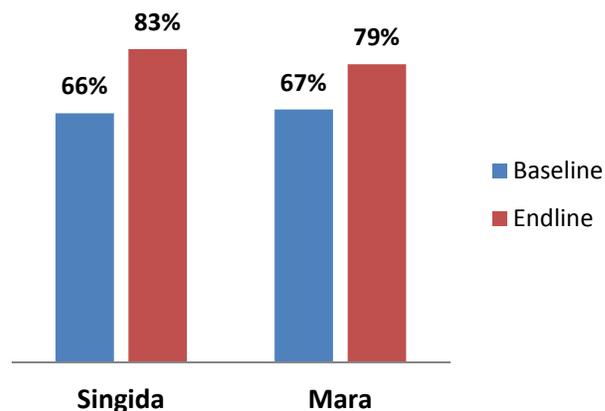
Table 2. Availability of antimalarial medicines in Singida and Mara before and after ADDO roll out

| Tracer drug	Singida Pre # (%)	Singida Post # (%)	Mara Pre # (%)	Mara Post # (%)	Singida difference (percentage points)	Mara difference (percentage points)	Between-group difference (percentage points)	P-Value
Artemether-lumefantrine 20/120 6 x 4 tabs	1(3)	2(7)	1(3)	0	4	−3	7	P=0.131
Quinine injection	3(9)	4(14)	9(19)	7(22)	5	3	2	p=0.412
Sulfametopyrazine + pyrimethamine tabs	24(75)	19(66)	18(55)	28(88)	−9	33	−42	**p<0.05***
Sulfadoxine + pyrimethamine tabs	21(66)	24(83)	22(67)	25(79)	17	12	5	p=0.649

*Difference between regions was statistically significant.

Availability of antidiarrheal products

Oral rehydration solution (ORS) is the key product recommended for managing non-bloody diarrhea in children in Tanzania. In Singida, the intervention district, the availability of this product increased by 15% following the intervention (Figure 4a). In the control district there was no increase. Recently a number of different child health programs in developing countries have been promoting the use of zinc in non-bloody diarrhea in children. In Singida, where such programs did not exist, the availability of this product increased from zero to 28%. However, in the control district where such programs did exist, the product increased by a larger margin (Figure 4b). Table 3 shows availability of antidiarrheals.

Figure 4a. Percent of shops with ORS
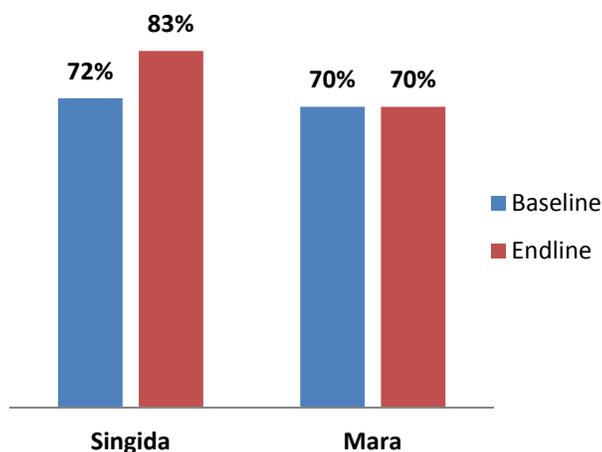
**Figure 4b. Percent of shops with zinc 20mg tablets**
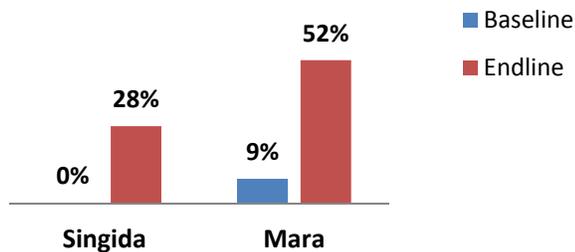
Table 3. Availability of antidiarrheal medicines in Singida and Mara before and after ADDO roll out

Tracer drug	Singida Pre # (%)	Singida Post # (%)	Mara Pre # (%)	Mara Post # (%)	Singida difference (percentage points)	Mara difference (percentage points)	Between-group difference (percentage points)	P-Value
ORS	23(72)	24(83)	23(70)	22(70)	11	0	11	p=0.204
Zinc tablets 20mg	0	8(28)	3(9)	17(52)	28	43	−15	**p<0.05***

*Difference between regions was statistically significant.

Availability of anti-infective medicines

Prior to the intervention, anti-infective medicines, by law, were not permitted to be stocked or sold in DLDB. However, most shops stocked and sold those products illegally. Following the implementation of the ADDO program in Singida, the availability of anti-infective medicines in drug shops increased significantly compared to Mara, the control region. For example the availability of amoxicillin capsules, the most frequently used antibiotic in the country, increased from 41% to 93% (Figure 5a). Mara, the control region recorded an insignificant increase of six percentage points (although sales in Mara should have been zero). Taking another frequently used anti-infective as an example, the availability of co-trimoxazole suspension increased from 25% at baseline to 93% at endline in Singida (Figure 5b). In Mara there was an insignificant change from 33% to 52%. The between-group comparisons between Singida and Mara before and after the intervention were statistically significant (Table 4) The availability of other anti-infective medicines followed a similar trend to amoxicillin and co-trimoxazole.

Figure 5a: Percent of shops with amoxicillin caps 250mg
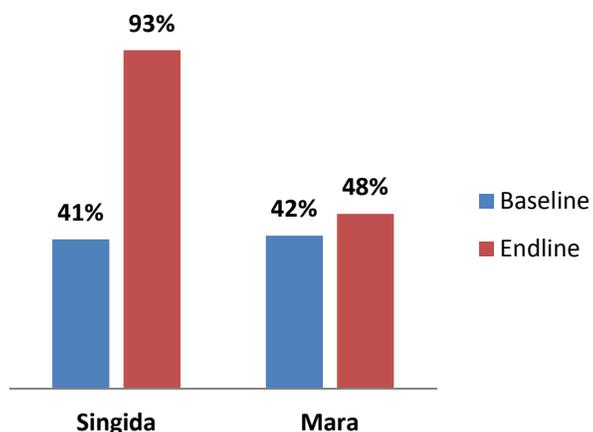
Figure 5b: Percent of shops with co-trimoxazole susp 200/40mg/5ml
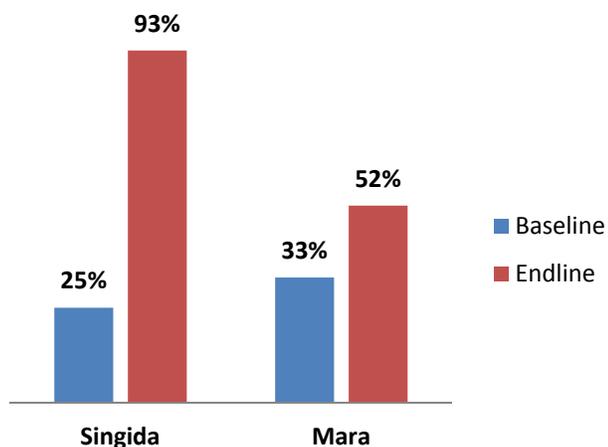

Table 4. Availability of selected anti-infective medicines in Singida and Mara before and after ADDO roll out

Tracer drug	Singida Pre # (%)	Singida Post # (%)	Mara Pre # (%)	Mara Post # (%)	Singida difference (percentage points)	Mara difference (percentage points)	Between-group difference (percentage points)	P-Value
Albendazole tabs 200mg	21(66)	23(79)	28(85)	24(75)	13	−10	23	P=0.689
Amoxicillin 250mg caps	13(41)	27(93)	14(42)	15(48)	52	6	46	**P<0.05***
Amoxicillin 125mg/5ml susp	14(44)	22(76)	11(33)	17(53)	32	20	12	P=0.065
Benzyl penicillin 5MU injection	2(6)	6(21)	3(9)	6(19)	15	10	5	P=0.849
Co-trimoxazole tabs 400/80mg	13(41)	26(90)	14(42)	21(66)	49	24	25	**P<0.05***
Co-trimoxazole susp 200/40 mg	8(25)	27(93)	11(33)	17(52)	68	19	49	**P<0.05***
Doxycycline tabs or caps 100mg	9(28)	20(69)	5(15)	10(31)	41	16	25	**p<0.05***
Erythromycin tabs 250mg	10(31)	25(86)	11(33)	14(44)	55	11	44	**p<0.05***
Erythromycin susp	8(25)	21(72)	8(33)	11(34)	47	1	46	**p<0.05***
Metronidazole tabs 200mg	17(53)	25(86)	19(59)	22(69)	33	10	23	p=0.105
Metronidazole susp	7(22)	14(48)	11(33)	17(53)	26	20	6	p=0.705

*Difference between regions was statistically significant.

Did ADDOs improve the quality of dispensing services in Singida?

An important component of the ADDO intervention is improved quality of services provided to drug shop clients. By training dispensers and accrediting shops, the intervention aims to have competent and skilled dispensers working within a supportive environment. To assess whether the program improved the quality of dispensing services, we used a simulated client or mystery shopper approach in Singida and Mara. The evaluation framework created two scenarios, one for a child with uncomplicated malaria and the other for a child with non-bloody diarrhea. Data collectors visited selected drug shops and simulated an interaction with the dispenser. The dispenser's responses during the interaction, including questions related to the child's condition and medicines he or she suggested or dispensed, were noted. Data collectors were trained to record all the key information as soon as they exited the drug shop. Observed practices (e.g., the medicines dispensed and the duration of therapy) were compared to national treatment guidelines to gauge appropriateness of the action. The data collectors also recorded standard dispensing practices, such as asking for symptoms when someone presented with a condition to rate dispenser practice.

Management of uncomplicated malaria

Although the standard treatment guidelines recommend AL for uncomplicated malaria, because Tanzania was facing a nationwide supply shortage, and little AL was available (Figure 3A), we considered dispensing either AL or SP at the correct dose and for the recommended time as "appropriate" treatment in Singida and Mara. Using the mystery shopper technique, we observed little difference between baseline and endline malaria treatment in Singida (Figure 6a). Also, appropriate malaria treatment in the control region dropped markedly. This would have been predicted in Mara if AL had been widely available, because unaccredited DLDB are not allowed to dispense AL—only ADDOs. This could mean that at endline, our data collectors were more stringent with their categorization of appropriateness than they were at baseline, although the same teams did both data collections.

Figure 6a: Percentage of malaria encounters with appropriate treatment
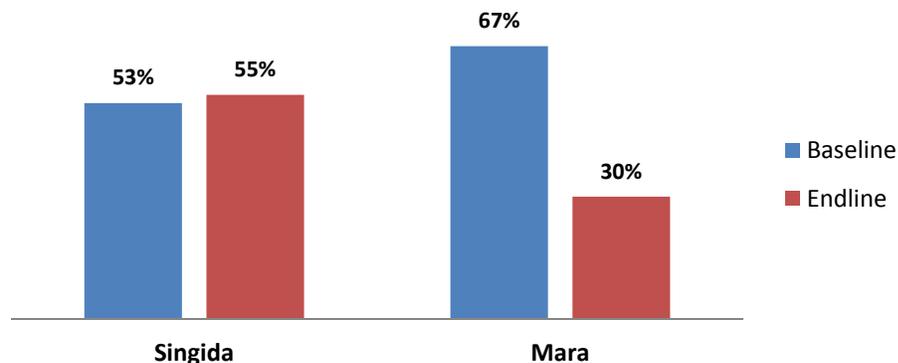
Management of non-bloody diarrhea

Overall, the mystery shopper exercise showed that the management of non-bloody diarrhea improved in Singida (Figure 6b). For example, the dispensing of antibiotics for non-bloody diarrhea decreased by 23% (98% baseline to 76% at end line) while in Mara, the control district, it remained relatively unchanged (84% baseline to 87% endline). The use of ORS increased from 20% to 33% in Singida, while Mara recorded a marginal difference pre and post intervention. There was no significant increase in the regions in the use of zinc, another recommended product for non-bloody diarrhea. This came as a surprising result for Mara, which had an intervention to promote the use of zinc running concurrently with the ADDO program. Although not statistically significant, these results show that although the management of non-bloody diarrhea improved marginally in the intervention district, practices still fall far short of the expected standard of care. Further intervention in this area is necessary.

Figure 6b: Percentage of non-bloody diarrhea encounters dispensed with medicines
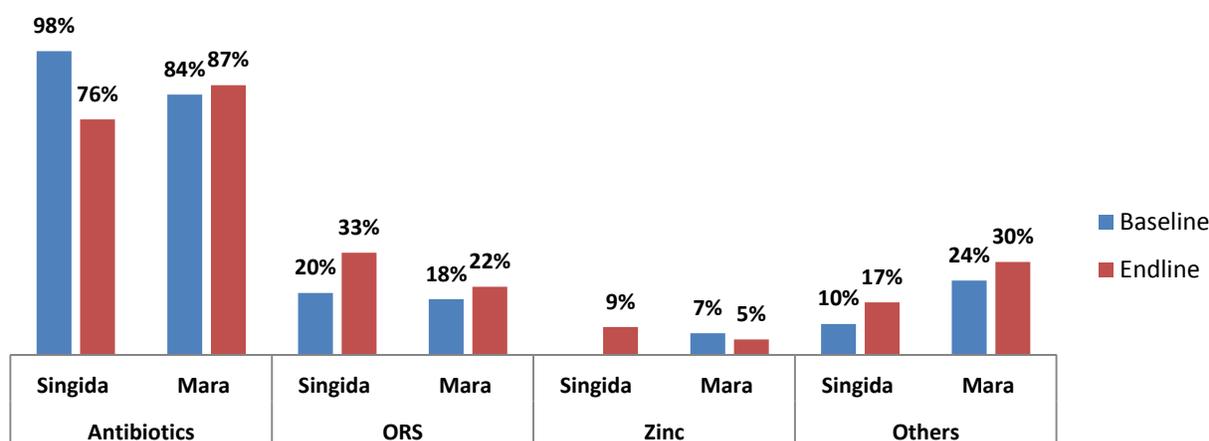
Quality of dispensing services

Singida showed some significant improvements in the quality of dispensing for both malaria and diarrhea compared to Mara. For the uncomplicated malaria case scenario, dispensers in the pilot region, Singida, improved against all indicators. The difference between the intervention and control regions was significant when looking at the following: asking about symptoms, giving instructions on how to take the medications, and giving information on how to look for danger signs (Table 5).

Table 5: Quality of dispensing services Singida vs. Mara—uncomplicated malaria

Indicator	Singida Pre # (%)	Singida Post # (%)	Mara Pre # (%)	Mara Post # (%)	Singida difference (percentage points)	Mara difference (percentage points)	Between-group difference (percentage points)	P-Value
Provider asked about child symptoms	25(47)	42(72)	27(60)	32(56)	25	−4	29	*p<0.05**
Provider asked if the child was taking any other medicines	13(25)	23(40)	19(42)	17(30)	15	−12	27	*P=0.16*
Provider gave instructions on how to take the medications	27(51)	47(81)	28(62)	34(60)	30	−2	32	*p<0.05**
Provider gave information on how to look for danger signs	3(6)	4(7)	1(2)	0	1	−2	3	*p<0.05**

*Difference between regions was statistically significant.

Similarly, for non-bloody diarrhea, there was statistically significant improvement in Singida for giving instructions on how to take the medications and giving information on how to look for danger signs. Other indicators measuring dispensing services showed no or minor improvement (Table 6).

Table 6: Quality of dispensing services Singida vs. Mara—non-bloody diarrhea

Indicator	Singida Pre #(%)	Singida Post # (%)	Mara Pre # (%)	Mara Post # (%)	Singida difference (percentage points)	Mara difference (percentage points)	Between-group difference (percentage points)	P-Value
Provider asked about child symptoms	32(78)	42(78)	30(67)	38(62)	0	−5	5	*P=0.229*
Provider asked if the child was taking any other medicines	11(27)	9(17)	11(24)	14(23)	−10	−1	−9	*P=0.559*
Provider gave instructions on how to take the medications	24(59)	46(58)	25(56)	36(59)	−1	3	2	*P= 0.140*
Provider gave information on how to look for danger signs	4(10)	10(19)	3(7)	1(2)	9	−5	14	***P<0.05***
Provider dispensed antibiotic	36(88)	39(80)	26(68)	54(88)	−8	20	−28	*P=0.198*
Provider dispensed ORS	8(20)	11(23)	7(16)	11(18)	3	2	1	*P=0.492*

*Difference between regions was statistically significant.

Did drug prices change following ADDO implementation in Singida?

Based on the tracer list, median prices of individual products increased more in Singida than in Mara, and also, more individual product prices increased (17 prices in the tracer list increased in Singida, while 11 individual prices increased in Mara); however both regions had prices that increased, decreased, and stayed the same. The median price for amoxicillin 250 mg tablets increased by 40% in Singida at endline, while it remained unchanged in Mara (Figure 7a). The price of artemether-lumefantrine slightly decreased in Singida (Figure 7b). We cannot explain the large difference in price for AL in Singida and Mara. In Singida, the median price for ORS increased by 50% (Figure 7c), while the median price for zinc 20 mg tablets decreased by 17% (Figure 7d). The price for ORS in Mara remained static between baseline and endline, while the decrease in price of zinc tablets was roughly proportional to Singida. .

The price increases in Singida seem to support the assertion that after incurring significant expenses in renovations, training, and increased inventory, ADDO owners need to recoup some of their expenses by raising prices. How this affects consumers' ability to buy essential medicines is unknown. In addition, ADDO owners may reduce prices after they earn back their initial investment.

Median prices for the full list of 30 tracer items are shown in Annex 6. In general, prices of all products were lower in Mara compared to Singida. This may be explained by the fact that Mara has a better road network, which makes it easier to supply DLDB in rural locations. However, average median prices for four tracer items (Figures 7a–7d) in Singida and Mara did not seem to parallel price changes In the *International Price Guide* (IPG) database.

Figure 7a: Median price for amoxicillin caps 250 mg (TZS)
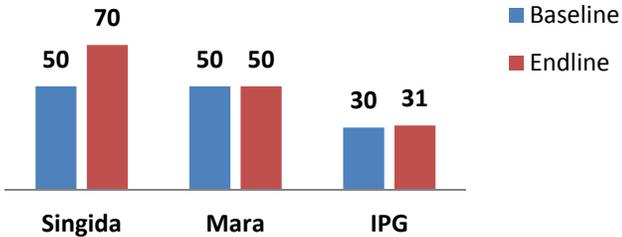
Figure 7b: Median price for AL (TZS)
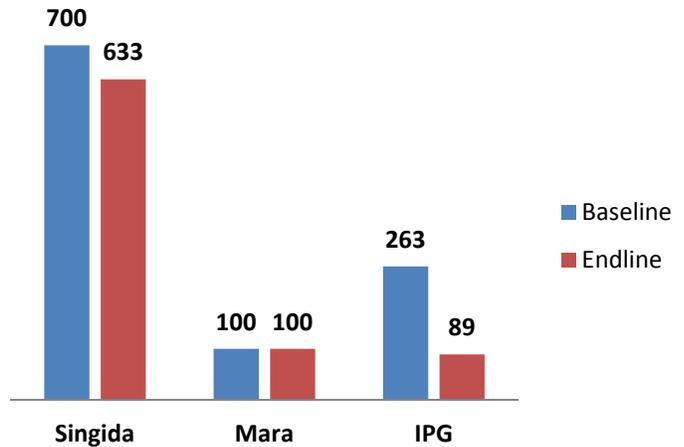
Figure 7c: Median price for ORS (TZS)
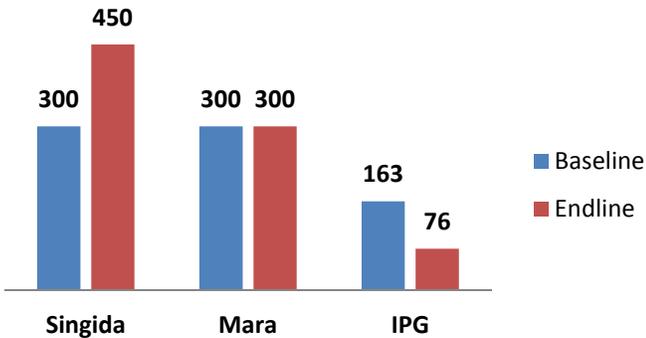
Figure 7d: Median price for zinc 20 mg tabs (TZS)
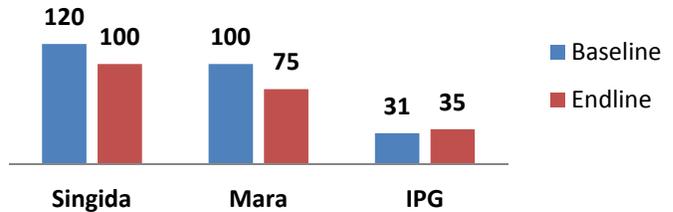
Is the decentralized approach to ADDO implementation cost-effective and are stakeholders satisfied with it?

While it took Tanzania 6 years to roll out the ADDO program in 4 regions using the original centralized implementation model, 10 more regions completed implementation within 3 years using the new decentralized approach. In addition, the decentralized implementation model resulted in significant reduction in rollout costs per district; TFDA estimated that the savings were greater than 50%. For example, in a district with 100 outlets to be accredited and 120 dispensers to be trained, the decentralized implementation model costs 73 million Tanzanian shillings (TZS) (~49,000 U.S. dollars [USD]) compared to 163 million TZS (~109,000 USD) under the centralized implementation model. Savings came primarily from a reorganized dispenser training schedule that was reduced from 45 to 26 days and the merging of mapping and preliminary inspection activities that are carried out by district officials rather than centrally based TFDA staff. Evaluation of product availability and service quality in Singida compared with Mtwara showed that these changes did not have significant negative impact on implementation results. In addition, owners and dispensers are paying bigger proportions of their training expenses—expenses that used to be covered by the government or a donor.

The average cost of accreditation to ADDO owners in Mtwara (centralized approach) was about 21% higher than in Singida (decentralized): 2,589,000 TZS (~1,599 USD) versus 2,145,000 TZS (~1,325 USD). In Singida, 93% of owners thought the money spent was well spent, as did 95% of owners in Mtwara. Accreditation in includes costs such as premises upgrade, increased medicine inventory, and training.

Over 60% of owners and dispensers in seven of nine districts in Singida reported good communication with TFDA and district authorities, while over 80% in the other two districts did not get regular feedback. All of the respondents in Mtwara felt that they received adequate financial and technical support from the central level during implementation.

This would be expected due to TFDA's hands-on approach under the centralized implementation model and indicates the need to pay more attention to communication under the decentralized implementation approach.

What broader efforts will help ensure scalability?

A number of elements contribute to how efficiently Tanzania can grow the ADDO program, including decentralizing the supportive supervision and inspection system to the district or ward levels, but retaining central TFDA support and oversight. In addition, policy and regulatory changes lead to the institutionalization of ADDOs into the government's health system. For example, in 2008, the Prime Minister's Office of Regional and Local Government mandated that districts include the ADDO program in their health planning budgets. These types of efforts not only facilitate scalability, but create sound infrastructure for program sustainability.

Local inspection system

One of the key components of the ADDO program is a decentralized regulatory system in which local inspectors at the ward and district levels are trained to conduct regular inspection visits. This is in addition to periodic inspections that TFDA inspection teams carry out from the zonal and central levels. Owners were asked to report how often they were inspected, and we verified this information by cross-checking the book in which inspectors are required to record their visits and findings. A majority of ADDOs (72% for Ruvuma and 52% for Mtwara) were inspected within the 12-month period prior to the survey and less than 10% had never been inspected (Figure 11). Inspection records were available in 73% of ADDOs in Ruvuma and 59% in Mtwara. Further record review indicated that 28% of ADDOs in Ruvuma were inspected by ward inspectors, 59% by district inspectors, and 5% by TFDA central and zonal level inspectors. For Mtwara, 52% of ADDOs were inspected by TFDA central, while ward level inspectors accounted for only 2% of inspections carried out. There are no comparable reports from 2004; however, quarterly inspection reports indicated that inspections by ward inspectors were carried out every three months in ADDOs in Ruvuma. The fact that inspection has been ongoing since program rollout in both regions seems to indicate that this component is indeed sustainable. It will need ongoing nurturing and monitoring, however.

Figure 11: ADDOs reported being inspected
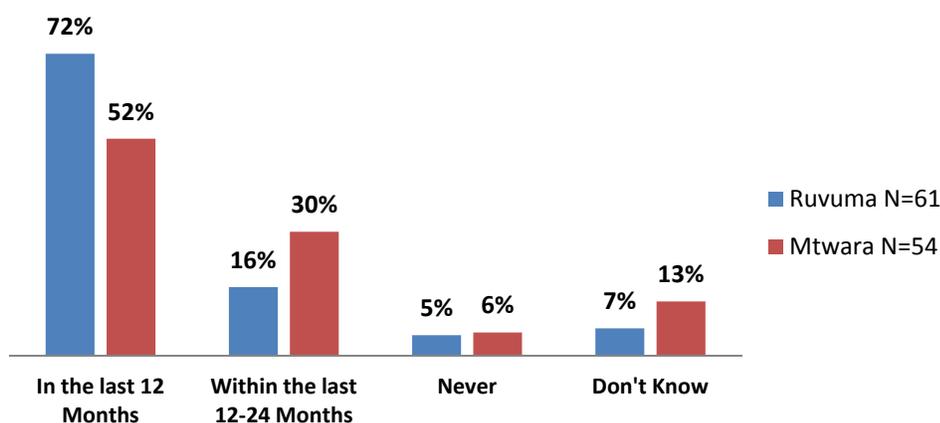
Institutionalization of ADDOs

One of the critical signs of institutionalization is inclusion of the ADDO program in the local government's budgetary process. In five regions (Ruvuma, Mbeya, Mtwara, Morogoro, and Singida), 23 of 25 districts (92%) included ADDO activities in their 2008–2011 health budgets. At the central level, Tanzania strengthened the ADDOs' place in the country's health system through a number of policy and regulatory changes, including the following—

- The National Malaria Control Programme identified ADDOs as a mechanism to supplement public-sector delivery of subsidized ACTs to increase access in rural and underserved areas.

- TFDA added ACTs to the existing limited list of prescription-only medicines that ADDOs are legally authorized to dispense.
- Child health interventions using the Integrated Management of Childhood Illness strategy[14] were integrated into the ADDO program.
- The National Health Insurance Fund accredits select ADDOs to provide products and services to its members.
- TFDA authorized ADDO scale-up in urban areas with underserved populations.

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[14] The Integrated Management of Childhood Illness, developed by the World Health Organization and the United Nations Children's Fund, targets the leading causes of childhood mortality: acute respiratory infection, diarrhea, malaria, malnutrition, and measles.

V.   Results Related to Sustainability (Tanzania)

Although a national-level champion is critical to a successful model launch, a mature program relies on the commitment of local officials to support inspection and supervision. Wide-ranging participation contributes to acceptance and sustainability. In terms of individual shop sustainability, our qualitative research under the EADSI program has shown that ADDO owners now keep business records (which is part of their training), their shops are profitable, and they use their profits to put money back into the business. Owners cite dispenser training and their expanded drug list as the biggest benefits to converting their shops to ADDOs.

Can the improvements in ADDO program be sustained beyond the pilot phase?

The ADDO program was piloted in Ruvuma region in 2003–2004 and was later scaled up in the Mtwara region in 2006–2007. To determine if ADDOs in Ruvuma and Mtwara have maintained the improvements, we assessed the availability of quality pharmaceutical products, quality of dispensing services, ADDO financial profitability, and the local inspection system. Where possible, we compared the indicators in Ruvuma across an eight-year span to measure how well the ADDOs were maintaining the quality of services: 2002 which was pre-implementation; 2004, which was post-implementation; and 2010, after the accredited shops had been operating for up to seven years.

Product availability

In Ruvuma in 2002, before the shops were legally allowed to sell antibiotics, availability of amoxicillin 250 mg capsules was at 69%. In 2004, after the introduction of the ADDOs, availability increased to 96%. In 2010, availability was at 83% (Figure 8). For metronidazole 200 mg tablets, availability was 83% in 2002, 98% in 2004, and 97% in 2010. These findings suggest that increased availability achieved during the ADDO program can be sustained.

**Figure 8: Average availability of select antibiotics in Ruvuma
2002-2010**
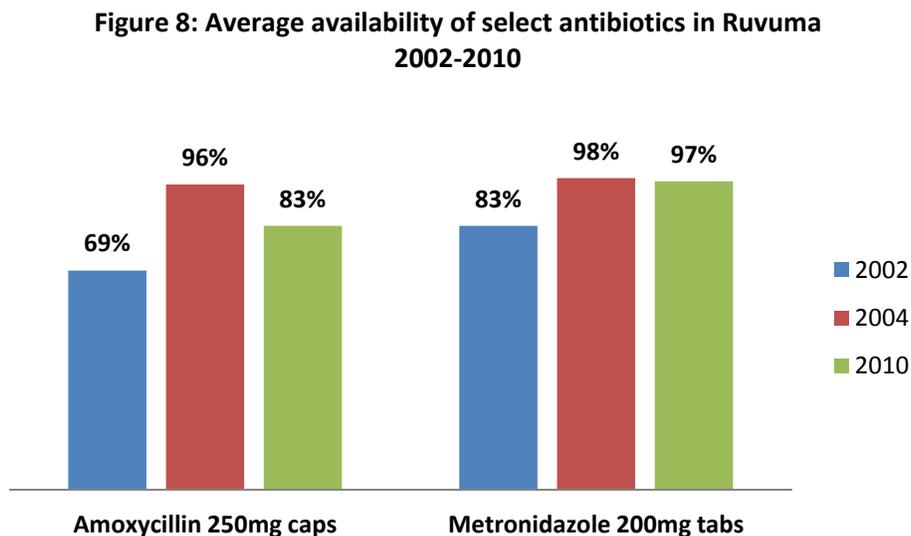
In most cases, the availability and prices of medicines are directly related to the efficiency of the supply chain system. Before the ADDO program was implemented in Ruvuma region, there were no wholesalers in the region. Ruvuma now has both wholesalers and ADDO-restricted wholesalers,[15] which also opened in other ADDO-implemented regions (although Mtwara has no ADDO-restricted wholesaler at present). To determine the adequacy of ADDO supply chain

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[15] ADDO Restricted Wholesaler is designated ADDOs that are allowed to operate as wholesalers distributors for all products that are legally allowed to be sold in the ADDO. One condition they need to meet that set them apart from ADDO is they need to be supervised and operated by a pharmacy technician registered by TFDA.

systems, owners in Ruvuma and Mtwara were asked where they buy their medicines. Over 90% of ADDOs in Ruvuma and Mtwara bought their medicines from wholesale pharmacies and 18% in Ruvuma used an ADDO-restricted wholesaler. About 42% of ADDOs in Ruvuma and Mtwara were within a 2-hour drive of a wholesale pharmacy, and 23% in Ruvuma were within a 2-hour drive from an ADDO-restricted wholesaler. Although supply options for ADDOs have improved significantly since 2004, efforts are needed to further improve product availability at the shops.

Quality of dispensing services

In general, the quality of pharmaceutical services delivered by ADDO dispensers in Ruvuma was maintained and for some indicators, and even improved. For example, the percentage of encounters where the customer received appropriate malaria treatment (that is, according to standard treatment guidelines in 2002, 2004, and 2010 and with the addition of SP in 2010 to accommodate AL shortages) has risen dramatically since the post-implementation evaluation (Figure 9). This also shows that improvements achieved implementation can be maintained.

Figure 9: Percentage of encounters with appropriate malaria treatment
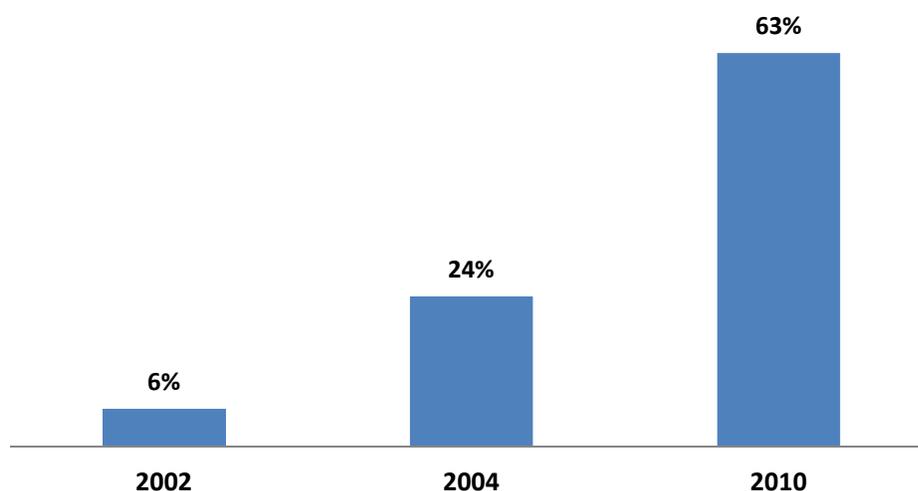
On the other hand, dispensing service indicators for uncomplicated malaria were inconsistent (Table 7). However, a significant improvement—decreased referrals—for uncomplicated malaria in 2010 was encouraging. Referring clients when a referral is not needed can be a sign of lack of confidence in making a decision. The over-referring that occurred in 2004, post-implementation in Ruvuma, could have indicated that providers were unsure of how to manage the condition.

Table 7: Quality of dispensing services for uncomplicated malaria

Did the drug seller—	2002 (%)	2004 (%)	2010 (%)
Ask about symptoms?	60	48	53
Ask about other medicines the child took?	37	54	43
Give instructions on how to take the medicine?	81	60	77
Recommend referral to a doctor or clinic?	32	52	17

Regarding management of non-bloody diarrhea, the percentage of encounters in which metronidazole was dispensed declined from 53% in 2004 to 42% in 2010. Although this is an improvement in terms of the assessment, it is still substandard practice because only ORS and zinc are recommended for non-bloody diarrhea. Further improvements will require additional investments because anecdotal evidence suggests that other factors beyond ADDO dispensing skills, such as physician prescribing practices, may contribute to the problem.

Shop profitability

At the time of the 2010 survey, 84% of ADDOs in Ruvuma (176/210) and 98% of shops in Mtwara (129/132) had been operating for more than two years. Shop closures in Ruvuma occurred due to a shortage of accredited dispensers, which are required to legally operate an ADDO. On the one hand, it is encouraging in that shops do not appear to operate illegally if an accredited dispenser is not available. On the other hand, shop closures decrease access to essential medicines in the affected communities. To address this gap for Ruvuma, TFDA, in collaboration with a private training institution, trained 206 dispensers in Ruvuma. It is noteworthy that the owners and dispensers who were trained paid almost entirely for this training through fees. As of March 2011, Ruvuma had 239 ADDOs in operation.

The figure below (Figure 10) shows that none of the shops surveyed in Ruvuma reported not making any profit at all. Compared to 2004, where a majority of ADDOs (62%) made a profit of less than 50,000 TZS per month, in the 2010 survey only 26% claimed that they made less than 50,000 TZS, while 44% reported making a net monthly profit of 100,000–500,000 TZS which is two to ten times higher. Note that the value of the TZS was about 30% less in 2004 compared with 2010 (~1,087 TZS to 1 USD in 2004 compared with ~1,430 TZS to 1 USD in 2010).

Figure 10: Average monthly net profit reported by ADDOs (TZS)
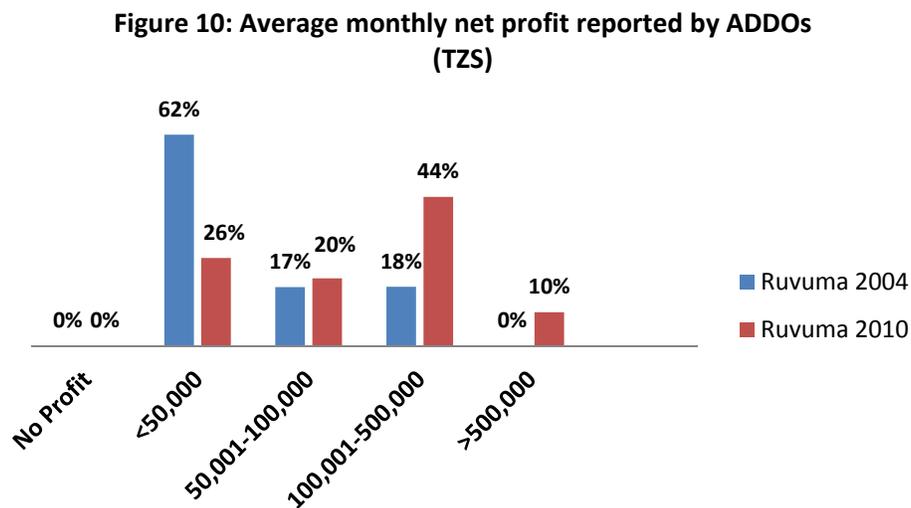
Did drug prices change in Ruvuma?

To be able to compare prices over the years that the ADDOs have operated in Ruvuma, we compared prices of tracer products to an average price in MSH's *International Drug Price Indicator Guide*, which is a proxy for the market price at that time. Ruvuma prices did not rise after ADDOs were introduced, but were higher in 2010 relative to the IPG prices in other years (Figures 11a and 11b).

Figure 11a: Average median unit price (TZS) compared to IPG for amoxicillin 250 mg caps
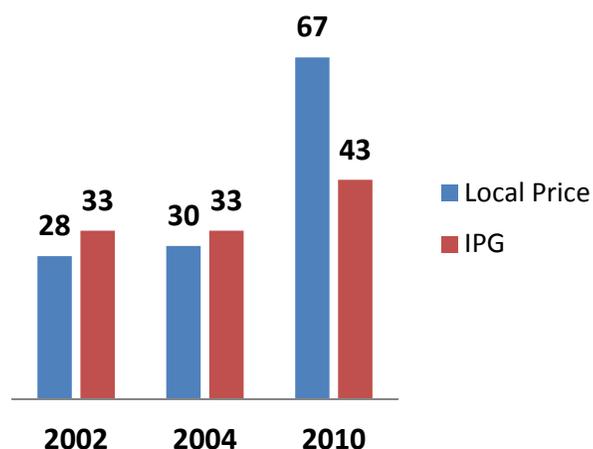
Figure 11b: Average median unit price (TZS) compared to IPG for co-trimoxazole 480 mg Tabs
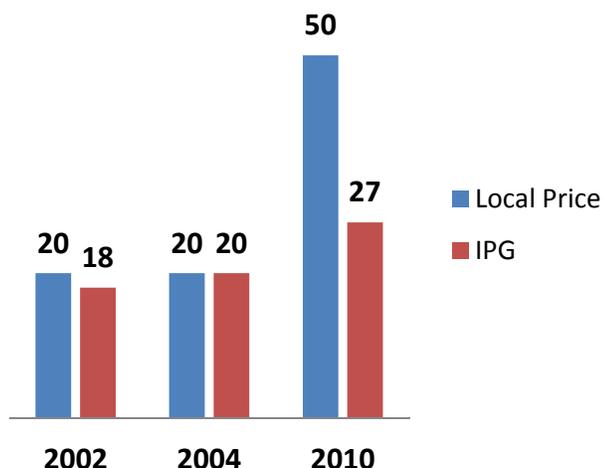
Do ADDOs satisfy community needs?

To assess whether accredited drug seller outlets appropriately address the needs of the communities they serve, EADSI conducted household surveys in Singida, Mara, and Ruvuma.

Disease burden

Household surveys measured the prevalence of both acute and chronic diseases in the three regions. An average of 50% of respondents reported that someone in the household had had an acute illness within two weeks of the survey. Eighteen percent reported that there was a person with a chronic illness in the house. The three regions surveyed had similar patterns for specific conditions (Table 8). For those who reported acute illness, 59% reported fever, 36% cough or other upper respiratory infections, and 8% vomiting or diarrhea. An average of 98% took medicines for the acute illness. The top four chronic diseases reported were hypertension and cardiovascular disease at 27%; asthma, 14%; arthritis, 13%, and ulcers, 12%. An average of 78% of those with chronic conditions took some sort of medication for it.

Table 8: Disease burden—Tanzania

	Ruvuma	Singida	Mara
Households reporting acute illness	43%	54%	53%
Households reporting chronic illness	17%	21%	16%
Households with acute or chronic condition that sought health care in previous two weeks	94%	92%	95%

Consumer satisfaction

In Ruvuma, an area that had the ADDO program running for over seven years, 86% of respondents to the household survey reported that they routinely obtained most of their medicines from ADDOs. In Singida, this figure was 85% at both baseline and endline. In Mara, this figure was 79% and 94%, respectively (Table 9). Households in Ruvuma chose ADDOs because 79% felt that the dispensers in ADDOs were knowledgeable.

Table 9: Consumer satisfaction—Tanzania

Indicator	Singida		Mara		Ruvuma
	Baseline	Endline	Baseline	Endline	2010
Households that routinely obtain most of their medicines from drug shops	85%	85%	86%	94%	86%
Households whose perception is that drug shop attendants are knowledgeable	48%	77%	79%	57%	79%
Households that report that they can buy medicines on credit from drug shops	31%	31%	58%	46%	42%

VI.   Results Related to Transferability (Uganda)

Because the challenges of access to essential medicines cuts across the African continent and other developing countries, one of the key objectives of the EADSI program was to design a program that was transferable. Transferability would benefit many other countries that faced the same challenges as Tanzania. Problems of quality of services in drug shops in Uganda are not dissimilar to those in Tanzania. To demonstrate transferability, EADSI sought to implement a similar pilot in one district in Uganda. The EADSI program thus worked with national and local stakeholders to develop an accreditation model based on the Tanzanian ADDO initiative, but adapted to the Ugandan context. With the Ministry of Health providing overall policy guidance, the National Drug Authority (NDA), the initiative's lead implementer, in collaboration with the Pharmaceutical Society of Uganda and Management Sciences for Health, selected two districts, Kibaale and Mpigi, to serve as the demonstration and control districts, respectively, for the new initiative. The maps in Annex 7 show the results of EADSI's global positioning system (GPS) mapping of both districts' health facilities and pharmaceutical outlets.

At the end of the pilot, 73 Class C drug shops (the equivalent of the DLDB in Tanzania) were accredited to operate as Accredited Dispensing Shops (ADS). A total of 246 drug sellers and 82 owners were trained in proper dispensing and business skills. To strengthen the regulatory system for ADS, health assistants were trained as local monitors to report drug shop regulatory violations to NDA.

Did ADS improve the availability of pharmaceutical products?

As in Tanzania, medicines in Uganda are categorized into prescription-only medicines (Class B) sold only in pharmacies and over-the-counter medicines (Class C), which can be sold in pharmacies or drug shops. To assess the availability and prices of medicines in Kibaale and Mpigi districts, we used a tracer list of 30 drugs (Annex 3). The tracer list included both Class B and Class C drugs. NDA provisionally allowed ADS to sell a limited list of certain Class B medicines, such as antibiotics, as part of the pilot initiative. Therefore, all of the Class B items on the tracer list were approved for sale in ADS in Kibaale, but were not approved for sale by Class C drug shops in Mpigi.

Annex 8 includes the availability results on the full list of tracer drugs classified by Class B and Class C.

Availability of Class B (prescription only) vs. Class C (non-prescription) medicines

The availability of both Class B (prescription only) and Class C (non-prescription) drugs increased in Kibaale compared with smaller increases for Mpigi (Figures 14a, 14b). The greatest increase in availability was for Class B drugs in Kibaale, which would be expected because ADS were allowed to sell certain prescription medicines.

Figure 14a: Product availability-Class B
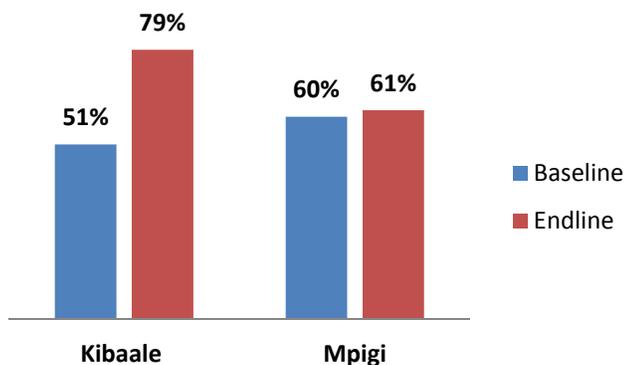
Figure 14b: Product availability-Class C
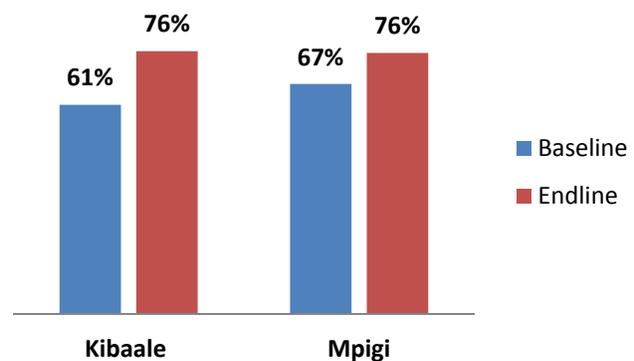
Availability of antimalarial medicines

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The availability of the recommended first-line antimalarial medicine for uncomplicated malaria, artemether-lumefantrine, increased in both the intervention district (Kibaale) and control (Mpigi) (Figure 15). These increases could have been affected by other concurrent interventions. However, a dramatic fall in the availability of chloroquine and sulfadoxine-pyrimethamine (SP) in Kibaale, but not in Mpigi, appears to be a result of the intervention. Table 10 shows availability data for antimalarials.

Figure 15: Availability of antimalarials at baseline and endline
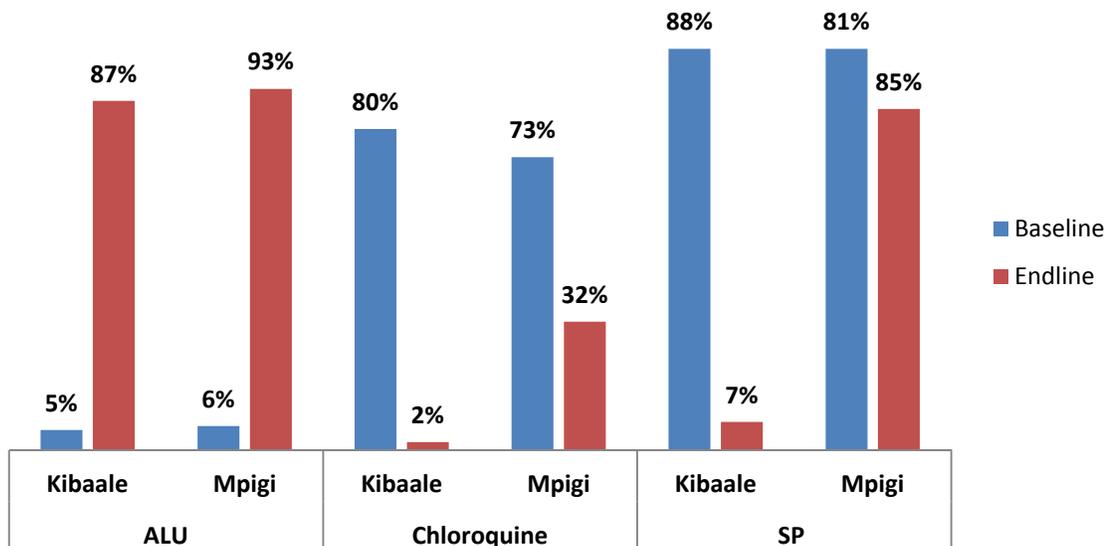
Table 10: Availability of Antimalarials in Kibaale and Mpigi

Tracer drug	Kibaale Pre # (%)	Kibaale Post # (%)	Mpigi Pre # (%)	Mpigi Post # (%)	Kibaale difference (percentage points)	Mpigi difference (percentage points)	Between group difference (percentage points)	P-Value
Artemether-lumefantrine 20/120 6 x 4 tabs	3(5)	39(87)	6(6)	38(93)	82	87	−5	p=0.291
Sulfametopyrazine+ pyrimethamine tabs	10(15)	0	17(27)	0	−15	0	15	p=0.523
Sulfadoxine + pyrimethamine tabs	58(88)	3(7)	52(81)	35(85)	−81	4	−77	**p<0.05**
Quinine injection	39(59)	1(2)	26(41)	18(44)	−57	3	54	**p<0.05**
Zinc tabs	6(6)	28(62)	8(13)	10(24)	56	11	45	**p<0.05**

Availability of antidiarrhea medicines

The number of ADS in Kibaale stocking ORS increased from 50% to 87%, while ADS stocks of zinc tablets increased from 6% to 62%. The number of drug shops in Mpigi also experienced smaller increases in the availability of antidiarrhea medicines (78% to 88% for ORS and 13% to 24% for zinc). Table 11 gives specific percentage availability of different drugs and makes statistical comparisons of the significance of the observed changes. The results for ORS are not statistically significant while those for zinc tablets are.

Table 11: Availability of Anti-diarrheal Products in Kibaale and Mpigi

Tracer drug	Kibaale Pre # (%)	Kibaale Post # (%)	Mpigi Pre # (%)	Mpigi Post # (%)	Kibaale difference (percentage points)	Mpigi difference (percentage points)	Between group difference (percentage points)	P-Value
ORS	33(50)	39(87)	50(78)	36(88)	37	10	27	*p=0.576*
Zinc tabs	6(6)	28(62)	8(13)	10(24)	56	11	45	***p<0.05***

*Difference between regions was statistically significant

Availability of injectables

Injectables by law are not supposed to be sold in either Class C shops or ADS. Yet at baseline, drug shops in both Kibaale and Mpigi stocked these items. At endline, no ADS in Kibaale had injectables available (Figure 16). Practices in Mpigi, on the other hand, remained unchanged.

Figure 16: Availability of injectables at baseline and endline
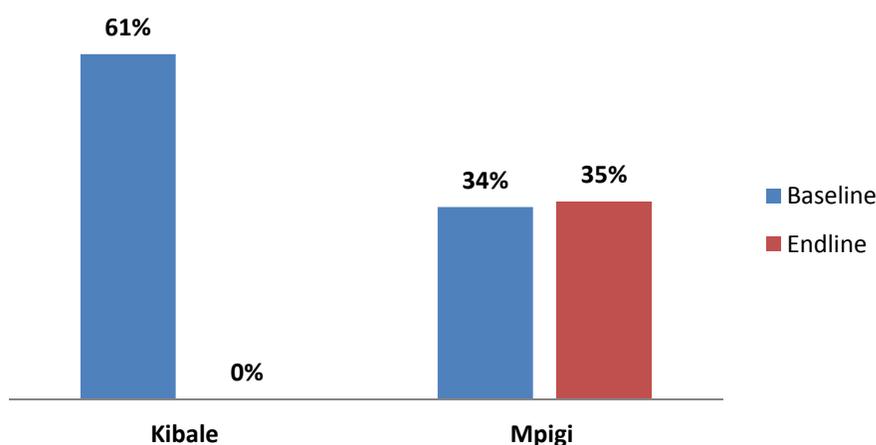
Availability of other medicines

The availability of most other medicines, including antibiotics, showed significant increases in Kibaale compared to Mpigi. Statistical tests showed that most differences were statistically significant (Table 12).

Table 12: Availability of Selected Other Medicines in Kibaale and Mpigi

Tracer drug	Kibaale Pre # (%)	Kibaale Post # (%)	Mpigi Pre # (%)	Mpigi Post # (%)	Kibaale difference (percentage points)	Mpigi difference (percentage points)	Between group difference (percentage points)	P-Value
Albendazole 200mg tabs	18(27)	30(66)	30(47)	23(56)	39	9	30	*P<0.05*
Amoxicillin 250mg caps	44(67)	42(93)	44(69)	26(63)	26	−6	32	*P<0.05*
Amoxicillin 125mg/5ml susp	34(52)	40(89)	37(58)	26(63)	37	5	32	*P<0.05*
Benzyl penicillin 5MU injection	41(62)	0	19(30)	14(34)	−62	4	−58	*P<0.05*
Co-trimoxazole 480mg tabs	51(77)	42(93)	53(83)	31(76)	16	−7	23	*P<0.05*
Co-trimoxazole susp	45(68)	38(84)	37(58)	21(51)	16	−7	23	*P<0.05*
Doxycycline 100mg caps or tabs	28(42)	37(82)	39(61)	24(59)	40	−2	42	*p<0.05*
Erythromycin 250mg tabs	34(52)	36(80)	34(53)	22(54)	28	1	27	*p<0.05*
Metronidazole 200mg tabs	38(58)	37(82)	51(80)	32(78)	24	−2	26	*p=0.414*

Did ADS improve the quality of dispensing services?

As in Tanzania, we sought to assess the quality of dispensing services in Uganda's Kibaale district before and after the intervention using mystery shoppers. EADSI assessed the appropriateness of uncomplicated malaria treatment and dispensing practices for a child under five years of age. The percentage of encounters with appropriate dispensing in Kibaale rose from 6% to 68% following the intervention (Figure 17). However, there was also an increase in the appropriateness of malaria management in Mpigi, the control district, although the margin of the increase was smaller. The increase in Mpigi could have been related to other ongoing malaria interventions. In general, dispensing practices improved in Kibaale after the advent of ADS (Table 13), but none of the results were statistically significant.

Figure 17: Percentage of encounters with appropriate malaria treatment
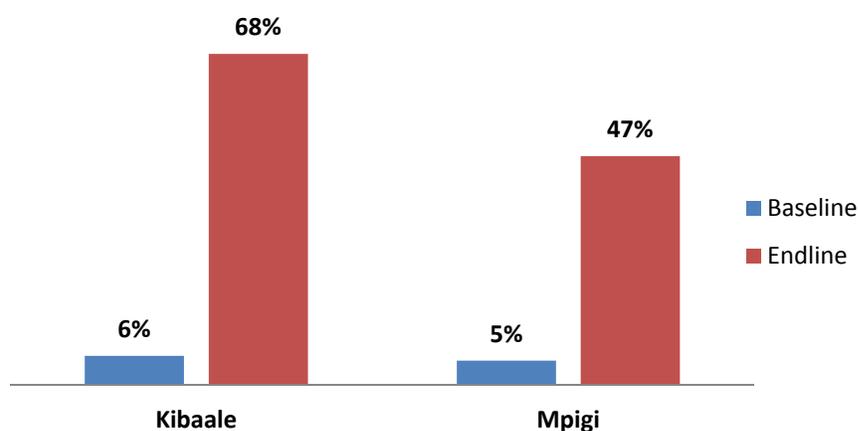
**Table 13: Quality of Dispensing Services Indicator at Baseline and Endline for Uncomplicated Malaria**

Indicator	Kibaale Pre # (%)	Kibaale Post # (%)	Mpigi Pre # (%)	Mpigi - Post # (%)	Kibaale difference (percentage points)	Mpigi difference (percentage points)	Between group difference (percentage points)	P-Value
Provider asked about child symptoms	9(56)	18(60)	15(75)	9(43)	4	−32	28	P=0.136
Provider asked if the child was taking any other medicines	5(31)	18(60)	8(40)	9(43)	29	3	26	P=0.136
The provide gave instructions on how to take the medications	12(31)	19(63)	14(70)	11(52)	32	−18	50	P=0.271
The provider recommended referral to a doctor or clinic	1(6)	3(10)	0	1(5)	4	5	−1	P=0.892

Did drug prices change following ADS implementation?

The median unit prices for a majority of products showed slight changes (both increases and decreases) after implementation of ADS in Kibaale. For example, the median price for the antimalarial, AL, decreased by an average of 19% in Kibaale and Mpigi, which reflects increased supply of ACTs following NDA's deregulation of importation (Figure 17a). The median unit price for amoxicillin capsules 250 mg showed no changes from baseline to endline in either district (Figure 17b).

Figure 17a: Median unit price of AL (UGX)
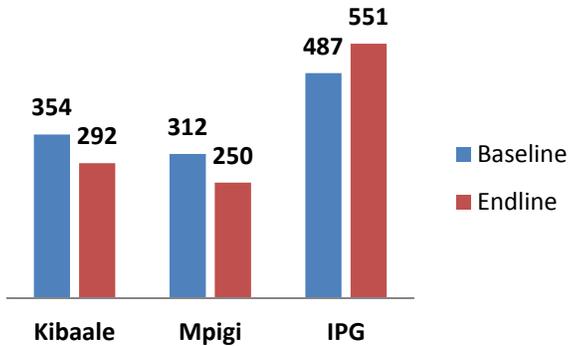
Figure 17b: Median unit price of amoxicillin caps 250 mg (UGX)
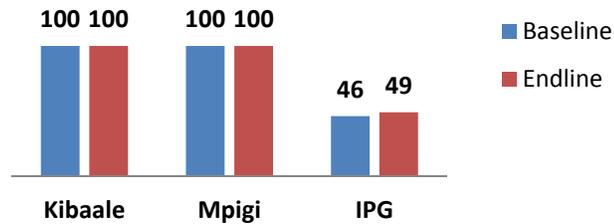
The median unit prices for antidiarrhea products (ORS and zinc) showed slight increases in both Kibaale and Mpigi at endline (Figures 17c and 17d). As in Tanzania, the median unit prices for most products were higher than the International Price Guide (Figures 17a-d). Median prices for the full list of 30 tracer items are shown in Annex 9.

Figure 17c: Median unit prices of ORS (UGX)
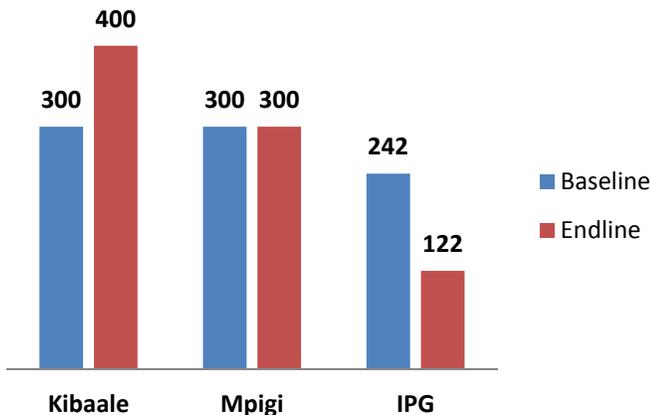
Figure 17d: Median unit prices of zinc 20 mg tabs (UGX)
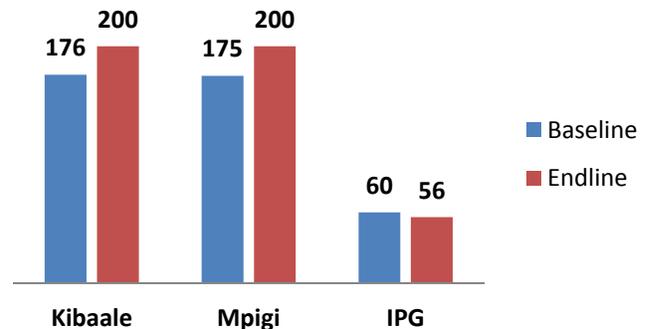
Did key stakeholders express satisfaction with the ADS pilot in the Kibaale district?

Interviews with ADS stakeholders showed general satisfaction with the accreditation concept and the implementation process. The main reason that owners cited for participating in the initiative was the expanded list of allowable drugs for sale. The expanded list, which includes select antibiotics, makes ADS more profitable. "*We no longer have to run away when the inspectors come because we are now allowed to have antibiotics,*" said an owner from Muhorro village. ADS owners paid an average of 700,000 Ugandan shillings (UGX) (~268 USD) to renovate their shops to meet accreditation standards. Ninety percent of the owners interviewed felt the cost was worth the investment. "*The customers have now increased; they see the business clean and organized, and we even have most of the medicines they want*"—ADS seller in Kasimbi village.

Sellers liked the opportunity to increase their skills to deliver quality services and therefore their social status. A seller from Buronzi village said*, "They now refer to us as abasawo batufu* (true doctors) *because we now know what we do, and we are held with high esteem in society*."

All the shop owners and sellers (n=64) who were interviewed post-intervention appreciated inspectors' visits, saying that they "*give us advice that is helpful to the business*." This was a changed attitude from before to the intervention: "*I

don't mind NDA or district inspectors, NDA used to be very hostile to us; it's now like eating on the same plate with a lion. They are all very supportive"—ADS owner from Kagadi.

Local authorities in Kibaale appeared to have accepted and supported the ADS concept by the time of endline data collection. For example, the Kibaale Secretary of Health said, "*ADS is very good, we are now budgeting for it in our integral activities for health. We pay staff to do support supervision for ADS, which we used not to do. We also facilitate by giving them transport. Even in our sensitization and mobilization activities, ADS is now included. If you look at our meeting minutes notes you can see ADS featured strongly. ADS have really helped our people supplement the government in provision of quality health services. We are proud of it, and I am extremely satisfied with the ADS implementation in Kibaale.*" In support of this, NDA included sensitization and supportive supervision activities in its budget for Kibaale.

Does ADS satisfy community needs?

To assess whether ADS appropriately address the needs of the communities they serve, EADSI conducted household surveys. The surveys also measured the prevalence of both acute and chronic diseases in Kibaale and Mpigi and assessed the level of consumer satisfaction with drug sellers in the community.

Disease burden

In the two districts, an average of 63% of the households surveyed reported an acute disease condition in the household, while chronic conditions were reported by an average of 33%. (Table 13). An average of 93% of households that reported an acute or chronic condition sought medical attention within the previous two weeks.

Table 13: Disease burden—Uganda

Indicator	Kibaale	Mpigi
Households reporting acute illness	64%	61%
Households reporting chronic illness	31%	34%
Households with acute or chronic condition that sought health care in previous two weeks	94%	92%

Consumer satisfaction

The percentage of households whose perception was that drug sellers were knowledgeable on the use of medicines did not change at endline (Table 14). Close to 100% of households surveyed in Kibaale and Mpigi at baseline reported that they routinely buy medicines from Class C drug shops. Households that reported that they routinely obtained medicines from drug shops decreased in Kibaale at endline. This decline could have been because clients visited less frequently after drug shops stopped providing certain services, such as injections. At baseline, only 10% of households in Kibaale reported that drugs shops were their first choice to access health care. By endline, that percentage had increased to 23%. In Mpigi, the percentage was 12 at baseline and 15 at endline.

Table 14: Consumer satisfaction—Uganda

Indicator	Kibaale		Mpigi	
	Baseline	Endline	Baseline	Endline
Households that routinely obtain most of their medicines from drug shops	93%	64%	98%	94%
Households whose perception is that drug shop attendants are knowledgeable	80%	80%	73%	76%
Households that report that they can buy medicines on credit from drug shop	0%	0%	1%	1%

VII.   Limitations of the Evaluation

Availability of data

One of the main limitations of the evaluation was the lack of data in regions that rolled out the program in the first phase, Ruvuma and Mtwara. Ruvuma's data did not cover all the indicators of interest to the EADSI program; we had no pre-intervention data from Mtwara. It was therefore a challenge to infer to sustainability across all EADSI M&E indicators. In addition, the approaches to evaluation during the centralized model implementation and during EADSI (decentralized model) were not necessarily the same, which also made comparisons challenging. Because we did not conduct household surveys during the earlier programs, we were unable to compare perceptions and attitudes between the two implementation models.

Sample size

Due to resource limitations, the sample sizes included in the different components of the evaluation were small. Apart from the price and availability surveys, where the WHO/HAI methodology recommends 30 outlets as a sample,[16] all other sample sizes were small. For household surveys, some experts recommend numbers of up to 3,000 to generate statistically significant results. For EADSI, we had the resources to survey 300 households per region. For the mystery shopping exercise, the numbers were particularly small, especially in Uganda. Because districts are small geographically, they have fewer drug shops to select for study. For Kibaale, there were slightly fewer than 100 Class C drug shops at baseline. We randomly selected half of these for the pricing and availability survey, while we targeted the rest for mystery shopping. Taking closures, logistics challenges, and refusals to participate into consideration, we ultimately visited fewer shops than expected. Because of these small numbers, changes which are clearly visible graphically were statistically insignificant.

Related to sample size was the issue of sampling. For the household surveys, the households selected were clustered around the drug shops where the price and availability survey was being conducted. This was done for convenience purposes and to maximize resources. Clearly, a limitation of this approach is that households further away from drug shops were left out of the exercise.

Interventions occurring concurrently

While EADSI was carrying out activities in Tanzania and Uganda, other interventions such as the Affordable Medicines Facility-malaria (AMFm), the zinc project in Mara, and the community health workers program in Kibaale began. The simultaneous activities could have masked the effects of the EADSI program. For example, if the purpose of AMFm was to provide AL at reduced prices to all drugs shops in Uganda, then the availability of AL would be high in both the intervention and control regions. Similarly, the zinc project in Tanzania, which was in Mara (the control region), would bias any significant increase in the availability and use of zinc for non-bloody diarrhea in Singida.

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[16] http://www.haiweb.org/medicineprices/manual/mp2008/NPrices_15.pdf

VIII.   Conclusions

Scalability of the ADDO initiative in Tanzania

- Is the decentralized ADDO implementation model effective in scaling up the ADDO program (Singida vs. Mara)?

  Evaluation of product availability and service quality in Singida compared with Mara showed that changes to the implementation model did not have significant negative impact on implementation results.

  Availability: As part of the ADDO program, TFDA regulations specifically allow ADDOs to sell a limited list of certain Part I (prescription only) medicines, such as antibiotics. All Part I items on the tracer list were approved for sale in ADDOs, but not in the non-accredited shops. As expected, the results show a larger increase in product availability in Singida compared to Mara for Part I drugs.

  Quality of dispensing services: Using the mystery shopper technique, we observed little difference between baseline and endline malaria treatment in Singida. Although not statistically significant, results show Singida experienced some improvement in the management of non-bloody diarrhea, but practices still fall far short of the expected standard of care. Further intervention in relation to case management is necessary. Singida showed some significant improvements in the quality of dispensing for both malaria and diarrhea compared to Mara. For the uncomplicated malaria case scenario, Singida dispensers improved relative to all indicators, and the difference was significant when looking at the following: asking about symptoms, giving instructions on how to take the medications, and giving information on how to look for danger signs. Similarly, for non-bloody diarrhea, there was statistically significant improvement in Singida for giving instructions on how to take the medications and giving information on how to look for danger signs.

  Drug prices: Median prices for the list of tracer items were lower in Mara (control) compared to Singida (intervention). The price increases in Singida seem to support the assertion that after incurring significant expenses in renovations, training, and increased inventory, ADDO owners recoup some of their expenses by raising prices. Prices need to be monitored periodically to determine if prices in Singida stabilize after costs of conversion have been recovered. In addition, comparison to an international benchmark needs to be periodically done. Based on the additional information, additional steps to stabilize or decrease prices may be warranted.

- Is the decentralized approach cost-effective and were stakeholders satisfied with it? (Singida vs. Mtwara)

  Cost-effectiveness: While it took Tanzania 6 years to roll out the ADDO program in 4 regions using the original centralized implementation model, 10 more regions completed implementation within 3 years using the new decentralized approach. In addition, the decentralized implementation model resulted in an estimated 50% reduction in rollout costs per district.

  Stakeholder satisfaction: In general, stakeholders under both the centralized and decentralized models expressed satisfaction. In Singida and Mtwara, almost all owners thought the money they spent was worthwhile. Over 60% of owners and dispensers in seven of nine districts in Singida reported good communication with TFDA and district authorities; however, over 80% in the other two districts did not get regular feedback. All of the respondents in Mtwara felt that they received adequate financial and technical support from the central level during implementation. This indicates the need to pay more attention to communication under the decentralized implementation approach.

- What broader efforts will help ensure scalability?

  Local inspection systems: One of the key components of the ADDO program is a decentralized regulatory system. Owners were asked to report how often they were inspected, and we verified this information by crosschecking the book in which inspectors are required to record their visits and findings. A majority of ADDOs (72% for Ruvuma and

52% for Mtwara) were inspected within the 12-month period prior to the survey and less than 10% had never been inspected at all. The fact that inspection has been ongoing since program rollout in both regions seems to indicate that this component is sustainable. It will need ongoing nurturing and monitoring, however.

Institutionalization of ADDOs: One of the critical signs of institutionalization is inclusion of the ADDO program in the local government's budgetary process. In 5 regions, 23 of 25 districts included ADDO activities in their 2008–2011 health budgets. At the central level, Tanzania strengthened the ADDOs' place in the country's health system through a number of policy and regulatory changes related to national health insurance, malaria treatment, and child health interventions.

Sustainability of the ADDO initiative in Ruvuma and Mtwara

- Can the ADDO program improvements be sustained beyond one year (Ruvuma and Mtwara)?

  Availability: Findings of a tracer list of essential medicines indicate that increased availability achieved during the ADDO program in 2004 was sustained until 2010. Before the ADDO program was implemented in Ruvuma region, there were no wholesalers in the region. Ruvuma now has both wholesalers and ADDO-restricted wholesalers,[17] which also opened in other ADDO-implemented regions (although Mtwara has no ADDO-restricted wholesaler at present). Over 90% of ADDOs in Ruvuma and Mtwara bought their medicines from wholesale pharmacies and 18% in Ruvuma used an ADDO-restricted wholesaler. Although supply options for ADDOs have improved significantly since 2004, efforts are needed to further improve product availability at the shops.

  Quality of dispensing services: In general, the quality of pharmaceutical services delivered by ADDO dispensers in Ruvuma was maintained and for some indicators, even improved. For example, the percentage of encounters where the customer received malaria treatment according to standard treatment guidelines has risen dramatically since the post-implementation evaluation. Fewer dispensers referred cases for uncomplicated malaria in 2010, which is a sign of knowledge and confidence. On the other hand, case management indicators for uncomplicated malaria were inconsistent. Further improvements will require additional investments because anecdotal evidence suggests that other factors beyond ADDO dispensing skills, such as physician prescribing practices, may contribute to the problem

  Drug prices: To be able to compare prices over the years that the ADDOs have operated in Ruvuma, we compared prices of tracer products to an average price in MSH's *International Drug Price Indicator Guide*, which is a proxy for the market price at that time. Ruvuma prices did not rise after ADDOs were introduced, but were higher in 2010 relative to the IPG prices.

- Are ADDOs in profitable (Ruvuma and Mtwara)?

  At the time of the 2010 survey, all of the shops surveyed in Ruvuma reported making profit. Compared to 2004, the amount of profit had also increased. It is noteworthy that the owners and dispensers who participated in a follow-up training in Ruvuma paid almost entirely for a follow-up training through fees; whereas during the pilot, the SEAM Program covered all costs.

- Do ADDOs satisfy community needs over time (Ruvuma, Mtwara, and Singida)?

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[17] ADDO Restricted Wholesaler is designated ADDOs that are allowed to operate as wholesalers distributors for all products that are legally allowed to be sold in the ADDO. One condition they need to meet that set them apart from ADDO is they need to be supervised and operated by a pharmacy technician registered by TFDA.

In Ruvuma, an area that had the ADDO program running for over seven years, 86% of respondents to the household survey reported that they routinely obtained most of their medicines from ADDOs. In Singida, this figure was 85% at both baseline and endline. In Mara, this figure was 79% and 94%, respectively. Households in Ruvuma chose ADDOs because 79% felt that the dispensers in ADDOs were knowledgeable.

Transferability of an accredited drug seller program to Uganda

- Was Tanzania's ADDO model effectively adapted and replicated for Ugandan context and needs?

  At the end of the pilot, 73 Class C drug shops were accredited to operate as ADS. A total of 246 drug sellers and 82 owners were trained in proper dispensing and business skills. To strengthen the regulatory system for ADS, health assistants were trained as local monitors to report drug shop regulatory violations to NDA.

  Availability: The availability of prescription medicines, including antibiotics, showed significant increases in Kibaale compared to Mpigi. The availability of the recommended first-line antimalarial medicine for uncomplicated malaria, artemether-lumefantrine, increased in both the intervention district (Kibaale) and control (Mpigi). However, a dramatic decrease in chloroquine and sulfadoxine-pyrimethamine in Kibaale, but not in Mpigi, appears to be a result of the ADS intervention. Injectables by law are not supposed to be sold in either Class C shops or ADS. Yet at baseline, drug shops in both Kibaale and Mpigi stocked these items. At endline, no ADS in Kibaale had injectables available. Practices in Mpigi, on the other hand, remained unchanged.

  Quality of dispensing services: EADSI assessed the appropriateness of uncomplicated malaria treatment and dispensing practices for a child under five years of age. The percentage of encounters with appropriate dispensing in Kibaale rose from 6% to 68% following the intervention. However, there was also an increase in the appropriateness of malaria management in Mpigi, the control district, which could have been related to other ongoing malaria interventions. In general, dispensing practices improved in Kibaale after the advent of ADS, but none of the results were statistically significant.

  Drug prices: The median unit prices for a majority of products showed slight changes (both increases and decreases) after implementation of ADS in Kibaale.

- Did key stakeholders express satisfaction with the pilot/demonstration of ADS intervention in the Kibaale district?

  Interviews with ADS stakeholders showed general satisfaction with the accreditation concept and the implementation process. The main reason that owners cited for participating in the initiative was the expanded list of allowable drugs for sale. Sellers liked the opportunity to increase their skills to deliver quality services and therefore their social status. Local authorities in Kibaale appeared to have accepted and supported the ADS concept by the time of endline data collection. In support of this, NDA included sensitization and supportive supervision activities in its budget for Kibaale.

- Do ADS satisfy community needs?

  The percentage of households whose perception was that drug sellers were knowledgeable on the use of medicines did not change at endline. Households that reported that they routinely obtained medicines from drug shops decreased in Kibaale at endline. This decline could have been because clients visited less frequently after drug shops stopped providing certain services such as injections. Close to 100% of households surveyed in Kibaale and Mpigi reported that they routinely buy medicines from Class C drug shops or ADS.

Challenges in Tanzania

Although the Ruvuma ADDO program has been maintained and enhanced since the launch in 2003–2004, challenges to the program's long-term sustainability nationwide remain. For example—

- Dispenser's training has not been institutionalized despite the readiness of some private training institutions to conduct training and the willingness of owners and dispensers to pay for training.
- Many district councils are including ADDO activities in their health plans and budgets; however, the amount set aside for ADDO activities may not be sufficient because of competing priorities.
- Legislative changes have shifted government responsibility for the ADDO program from TFDA to the Pharmacy Council; however, the Pharmacy Council's limited capacity may result in a difficult transition.
- Despite the observed improvement, some ADDO services still have room for improvement; for example, too many dispensers sell the antibiotic metronidazole for simple diarrhea instead of the recommended treatment, ORS and zinc.
- Regulatory enforcement varies greatly between districts because of a lack of inspectors, competing priorities for funding and personnel, and a limited number of central-level staff to support districts.
- ADDO rollout has not included outreach campaigns targeting consumer education and promotion related to ADDO services and appropriate use of medicines.
- ADDO owners' lack of access to new capital limits their ability to stock all the medicines they need. As a result, they are left out of some programs. For example, NHIF is reluctant to accredit ADDOs that cannot sufficiently stock all the medicines on its list.

Challenges in Uganda

Stakeholders, particularly shop owners and dispensers, were generally enthusiastic about the initiative, but challenges remain—

- Most ADS owners rent their premises (78% of those interviewed). Convincing property owners to do major renovations is difficult. Some shops were forced to relocate.
- Financial institutions focus on other sectors (e.g., agriculture), so getting a loan is harder for drug sellers; however, 100% (n = 64) of the owners interviewed said they faced no challenges to meeting the accreditation standards.
- Customers still demand ADS sellers to supply half doses and medicines outside the list.
- ADS face competition from illegal (unlicensed) sellers.
- More sellers need to be trained to fill openings caused by attrition and the accreditation of new shops.

Creating a Sustainable Private-sector Drug Seller Program in Tanzania

Funded by the Bill & Melinda Gates Foundation through a three-year grant, the East African Drug Seller Initiative (EADSI) aimed to increase access to quality medicines and pharmaceutical services in underserved areas through involvement of the private sector. EADSI built on Management Sciences for Health's Strategies for Enhancing Access to Medicines Program, also funded by Gates, and which, in collaboration with the government of Tanzania, launched the country's successful accredited drug dispensing outlet (ADDO) program. EADSI's goal was to create a sustainable accredited drug seller model that can be adapted, replicated, and scaled up in underserved regions of developing countries and that will ultimately operate independent of donor support.

Situation in Tanzania: The ADDO pilot showed improvements in access to quality medicines and pharmaceutical services in Ruvuma. However, successful pilot initiatives do not necessarily reflect what is needed to ensure successful national scale-up. Scaling up requires much more than simply adding staff and resources. The experience showed that greater efficiencies in implementation and some changes to the drug seller accreditation/regulation model were needed to enable Tanzania and other countries to institutionalize and sustain the initiative.

Strategy for Change: EADSI organized a stakeholder workshop in July 2008 to review ADDO implementation results and develop consensus on options for revising the existing model to help ensure successful ADDO scale up and financial sustainability. EADSI worked with Tanzanian stakeholders to revise the ADDO model and decentralize implementation, which allowed multiple regions to scale up concurrently while decreasing implementation costs and maintaining the quality and sustainability of the program.

Program Evaluation

Household interview in Mara

Decentralized implementation model. With changes to the ADDO model, EADSI needed to determine whether the new approach had reduced access to quality pharmaceutical products and services that had been originally demonstrated in the Ruvuma pilot. The decentralized ADDO implementation model was evaluated in 30 shops in Singida region, while 30 shops in Mara served as the control. Baseline and endline quantitative data collection on unaccredited drug shops and ADDOs in Singida and Mara used shop audits to assess availability and mystery shoppers to evaluate dispensing quality; 120 mystery shoppers in each region presented at unaccredited drug shops or ADDOs using the scenario of a child with simple malaria or nonbloody diarrhea. To gauge consumer satisfaction, EADSI conducted baseline and endline household surveys in Singida and Mara to assess medicine access and use behaviors and determine community health concerns. At baseline, we visited 308 households in Singida and 333 in Mara. Endline data represents 290 households in Singida and 328 in Mara.

EADSI also collected qualitative data to assess other differences between the centralized and decentralized rollout approaches. This data included interviews with drug shop owners, dispensers, and local authorities in Mtwara region, which implemented ADDOs using the centralized model, and in Singida region, which used the revised model. In addition, EADSI interviewed five central-level government representatives and seven national trainers.

ADDO program sustainability. To assess sustainability of the ADDO initiative, EADSI looked at business indicators such as profitability in Ruvuma, Mtwara, and Singida. In addition, to determine whether medicine availability and quality pharmaceutical services had been maintained over time, we evaluated the pilot region, Ruvuma, using shop audits and mystery shoppers. We visited 30 shops in Ruvuma and audited their products to assess availability. To evaluate dispensing quality, 120 mystery shoppers in Ruvuma visited ADDOs using the scenario of a child with simple malaria or nonbloody diarrhea. Household surveys in Ruvuma (301) determined consumer satisfaction and community health concerns and assessed medicine access and use behaviors.

Results: Decentralized Implementation Model

Product availability. The number of ADDOs with oral rehydration solution (ORS) available increased 15% (from 72% at baseline to 83% at endline) and ADDOs stocking zinc tablets increased to 28% from none at baseline. In Mara, the control region, ORS availability remained static, while zinc tablet availability jumped from 9% to 52% ($p<0.05$), due to the start of another regional initiative targeting diarrhea.

Percentage of Unaccredited Drug Shops and ADDOs with Antidiarrheals Available at Baseline and Endline
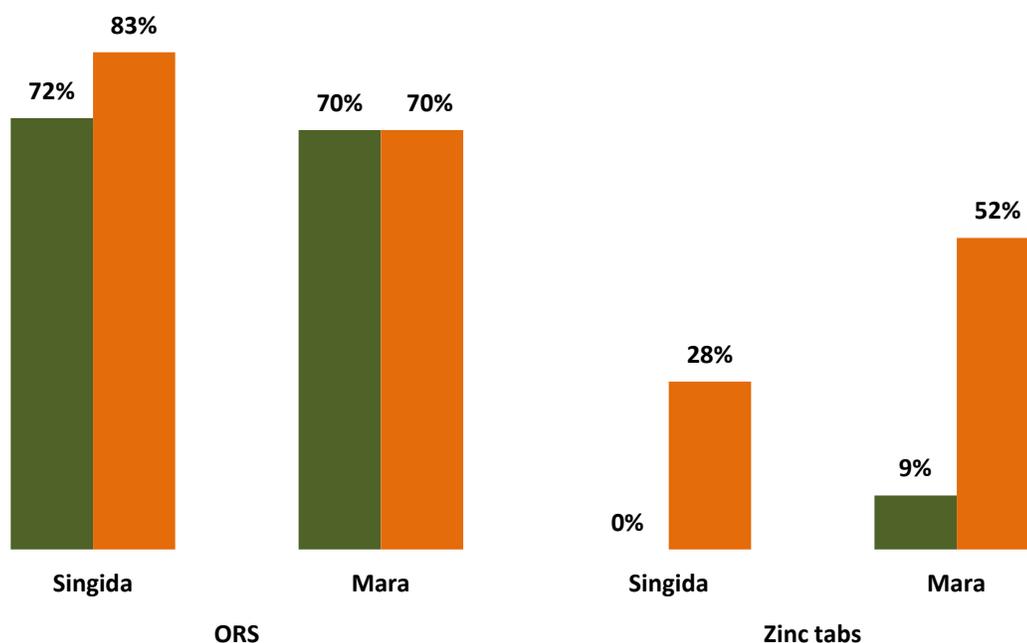
Quality of pharmaceutical services. The use of ORS and zinc is the recommended treatment for diarrhea. Dispensers in Singida dispensed antibiotics for diarrhea 23% less after the conversion to ADDOs (98% baseline to 76% at endline), while Mara remained basically unchanged (84% baseline to 87% endline). ORS and zinc use in Singida increased from 20% to 33% and from 0 to 9%, respectively. ORS and zinc use in Mara was also low. At baseline, ORS use was 18% and rose to 22%, while zinc use went from 7% to 5%. Although not statistically significant, the results show that ADDO dispensers improved their practices. Clearly, however, management of uncomplicated diarrhea is an area that needs further emphasis in both training and onsite supervision.

Dispensing service indicators for uncomplicated malaria improved after the ADDO intervention in Singida; however, future training should also address room for improvement.

Did the drug seller—	Singida		Mara	
	Baseline %	Endline %	Baseline %	Endline %
Ask about symptoms?*	47	72	60	56
Ask about other medicines the child took?	25	40	42	30
Give instructions on how to take the medicine?*	51	81	62	60
Give information on looking for danger signs?*	6	7	2	0

*$p < 0.05$

In addition, the percentage of malaria scenario mystery shoppers who were referred to a health facility increased in Singida from 13% at baseline to 19% at endline. Because ADDO training should result in drug sellers feeling confident about handling uncomplicated malaria, the referral rate post-implementation should have been zero.

Consumer satisfaction. EADSI conducted household surveys in the pilot region of Singida and the control region of Mara. At baseline, we interviewed participants from households in Singida and in Mara about their preferences regarding where to seek health advice, buy medicines, and their opinions about ADDOs in Singida or *duka la dawa baridi* (DLDBs) in Mara. Respondents in both Singida and Mara preferred to go to a public health facility for health advice. The most common reason given for choosing a public health facility for treatment was diagnostic capability, followed by the qualifications of providers.

When asked where their first choice was to buy medicines, 48% in Singida reported ADDOs at baseline and 56% at endline, an increase of 17%, while about 80% in Mara reported DLDBs at both baseline and endline. When asked why they chose drug shops, the most common answers at endline were availability of medicines (28% and 62% in Singida and Mara, respectively) and distance (58% in Singida and 28% in Mara).

Household Opinions Regarding ADDOs or *Duka la Dawa Baridi* at Endline

Legend: ADDOs in Singida, DLDBs in Mara.
Obtain most medicines from drug shops: 66%, 83%
Medicines are of good quality: 81%, 61%
Attendant is knowledgable: 77%, 59%
Prices are affordable: 56%, 38%
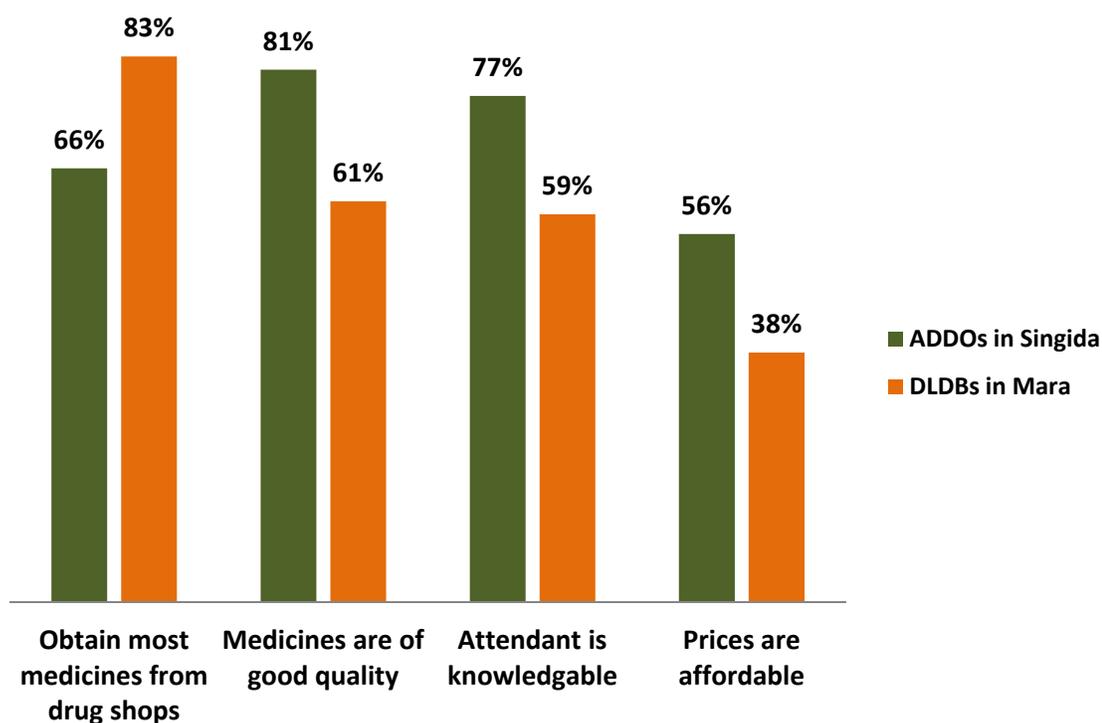
Time required for implementation. While it took Tanzania 6 years to roll out the ADDO program in 4 regions using the original centralized implementation model, an additional 10 regions completed implementation within 3 years using the new decentralized approach.

Cost of implementation. The decentralized implementation model resulted in a significant reduction in roll out costs per district. The Tanzania Food and Drugs Authority (TFDA) determined that the savings were greater than 50%. For example, in a district with 100 outlets to be accredited and 120 dispensers to be trained, the decentralized implementation model cost 73 million Tanzanian shillings (TSH) (~49,000 US dollars [USD]) compared with a cost of 163 million TSH (~109,000 USD) under the centralized implementation model. Savings came primarily from a reorganized dispenser training schedule that was reduced from 45 to 26 days and a merge of mapping and preliminary inspection activities to identify which drug shops are eligible to enter the accreditation program. Owners also pay all costs associated with shop renovations and increased inventories.

The average cost of accreditation to ADDO owners in Mtwara (centralized approach) was about 21% higher than the average in Singida: 2,589,000 TSH (~1,599 USD) versus 2,145,000 TSH (~1,325 USD). In Singida, 93% of owners thought the money spent was worthwhile, compared with 95% of owners in Mtwara. Accreditation includes costs such as premises upgrades, increased medicine inventory, and training.

Stakeholder satisfaction. In Singida, over 60% of owners and dispensers in 7 of 9 districts reported good communication with TFDA and district authorities, while over 80% in the other two districts, did not get regular feedback. All of the respondents in Mtwara felt that the financial and technical support received from central level was adequate during implementation.

> **"We now have good communication with TFDA people, they visit us to see how we are doing, and when we have expired drugs, we report it to the pharmacist who takes measures." (Dispenser, Singida Rural district)**
>
> **"The training gave me skills on how to acquire and pay loans, and now I am able to calculate what profit and loss I get in my shops. Also through this shop, I pay school fees for my children." (Owner, Singida Urban district)**
>
> **"The shop is now like a small pharmacy and many people see me as a professional dispenser." (Dispenser, Mtwara)**

Challenges with decentralized model. Challenges reported included districts without the resources to provide supportive supervision and the transfer of district officials who are familiar with the ADDO program, resulting in new staff members who need orientation. Some districts did not plan or budget for ADDO activities, while some who did plan, had not received approval yet. Stakeholders thought that communication between district government and the central level was inadequate.

Results: ADDO Program Sustainability

Where possible, we compared the indicators in Ruvuma across three different years to measure how well the ADDOs were maintaining their service quality: 2002 which was before the ADDO implementation; 2004, which was post implementation; and 2010, after the shops had been operating for up to seven years.

Retired nurses in ADDO dispenser training

Product availability. As part of the initiative, ADDOs were allowed to legally start selling a select list of prescription-only medicines, including a number of antibiotics. In 2004, the average availability of antibiotics in ADDOs was 77%, while in 2010, the average was 70%. In 2002, the average availability of antibiotics before the drug shops were allowed to sell them was 54%.

Over 90% of ADDOs in Ruvuma and Mtwara bought their medicines from wholesale pharmacies and 18% in Ruvuma used an ADDO-restricted wholesaler. (Mtwara has no ADDO-restricted wholesaler.) About 42% of ADDOs in Ruvuma and Mtwara were within a 2-hour drive of a wholesale pharmacy and 23% in Ruvuma were within a 2-hour drive from an ADDO-restricted wholesaler.

Quality of pharmaceutical services. In large part, the quality of pharmaceutical services delivered by ADDOs in Ruvuma was maintained and for some indicators increased. For example, the percentage of encounters where the customer received malaria treatment according to standard treatment guidelines has risen dramatically since the post implementation evaluation. This is very encouraging and shows that improvements can be maintained over the long term.

**Percentage of Encounters Receiving Malaria Treatment
According to Standard Treatment Guidelines in Ruvuma**
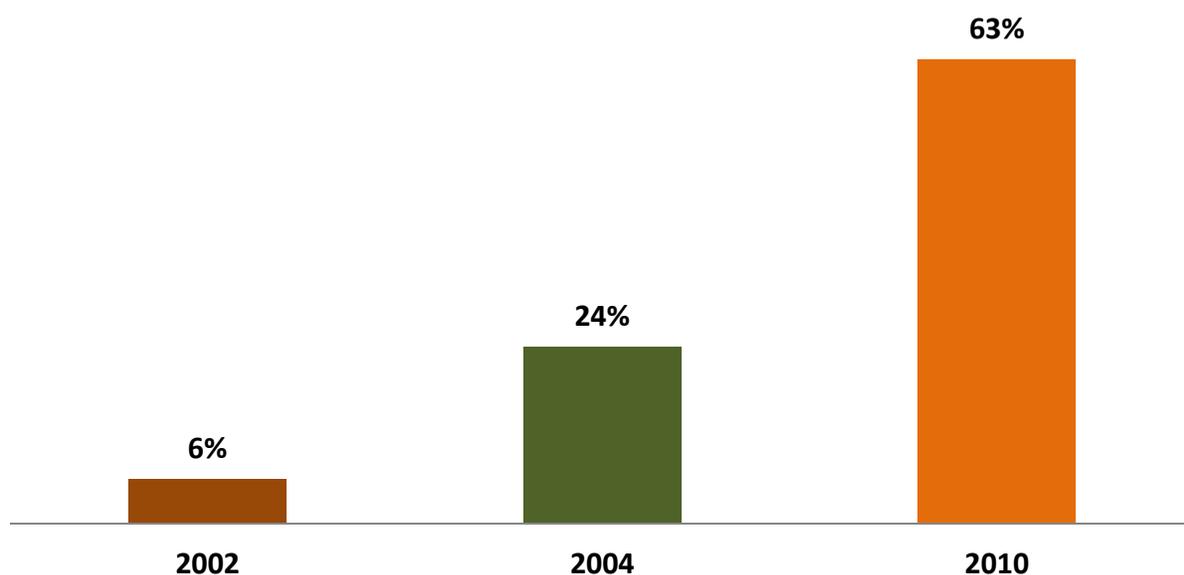
On the other hand, dispensing service indicators for uncomplicated malaria were unpredictable. A significant improvement (decrease) in referrals for uncomplicated malaria in 2010 was encouraging; however, dispensers should not be referring any cases of simple malaria to a health provider.

Did the drug seller—	2002 (%)	2004 (%)	2010 (%)
Ask about symptoms?	60	48	53
Ask about other medicines the child took?	37	54	43
Give instructions on how to take the medicine?	81	60	77
Recommend referral to a doctor or clinic?	32	52	17

Consumer satisfaction. In Ruvuma, 86% of respondents to the household survey reported that they routinely obtained most of their medicines from ADDOs—95% of those treating an acute illness turn to ADDOs for medicines. The primary reason Ruvuma residents chose ADDOs was because of the availability of medicines there (59%). In addition, 79% felt that the dispensers at ADDOs are knowledgeable.

Financial success of ADDOs. At the time of the survey, 84% of ADDOs in Ruvuma (176/210) and 98% of shops in Mtwara (129/132) had been operating for more than two years. Shop closures in Ruvuma were due to a lack of accredited dispensers, which ADDOs need to operate legally. However, TFDA collaborated with a private training

institution to train 206 dispensers in Ruvuma to fill the gap, and as of March 2011, Ruvuma had 239 ADDOs in operation.

The figure below shows that very few shop owners reported not making any profit at all. About 35% of all ADDOs in Singida, Mtwara, and Ruvuma made an average net profit of between 50,000–500,000 TZS per month with mature ADDOs in Ruvuma making the highest amount per month.

Average Net Profit per Month Reported by ADDO Owners in 2010 (TZS)
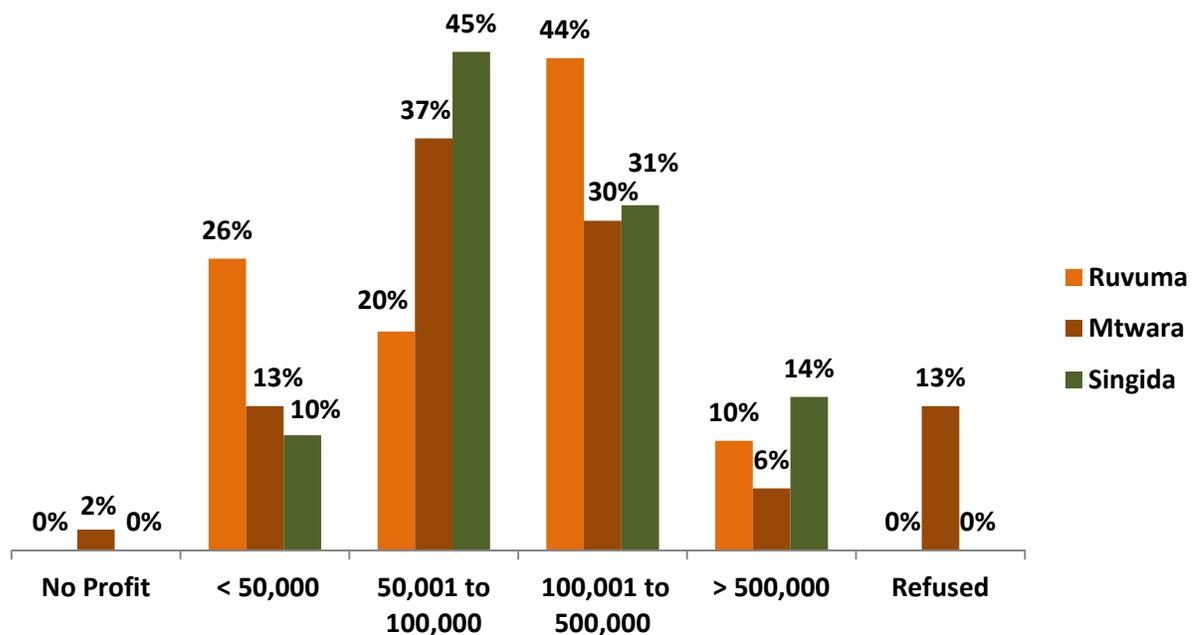
Institutionalization of ADDOs. One of the critical signs of institutionalization is local government acceptance of ADDOs through the budget process. In five regions, Mbeya, Mtwara, Morogoro, Ruvuma, and Singida, 23 of 25 districts (92%) included ADDO activities in their 2008–2011 health budgets. At the central level, Tanzania strengthened ADDOs' place in the country's health system through a number of policy and regulatory changes. For example—

- The National Malaria Control Programme identified ADDOs as a mechanism to supplement public-sector delivery of subsidized artemisinin-based combination therapy (ACT) to increase access in rural and underserved areas.

- TFDA added ACTs to the existing limited list of prescription-only medicines ADDOs are legally authorized to dispense.

- Child health interventions using the Integrated Management of Childhood Illness strategy were integrated into the ADDO program.

- The National Health Insurance Fund accredits ADDOs to provide products and services to its members.

- TFDA authorized ADDO scale-up in urban areas with underserved populations.

Challenges to sustainability. Although the Ruvuma ADDO program has been maintained and enhanced since the launch in 2003, challenges to the program's long-term sustainability nationwide remain. For example—

- Dispenser's training has not been institutionalized, despite the readiness of some private training institutions to conduct training and the willingness of owners and dispensers to pay for training.

- Many district councils are including ADDO activities in their health plans and budgets; however, the amount set aside for ADDO activities can be small because of competing priorities.

- Legislative changes have shifted government responsibility for the ADDO program from TFDA to the Pharmacy Council; however, the Pharmacy Council's limited capacity may result in a rough transition.

- Despite improvement overall, some ADDO services still have room for improvement; for example, too many dispensers sell the antibiotic metronidazole for simple diarrhea instead of the recommended treatment, ORS.

- Regulatory enforcement varies greatly between districts because of a lack of inspectors, competing priorities for funding and personnel, and a limited number of central-level staff to support districts.

- ADDO rollout has not included consumer education about or promotion of ADDO services and appropriate use of medicines.

ADDO supervision visit

- ADDO owners' lack of access to new capital limits their ability to stock all the medicines they need. For example, NHIF has refused to accredit ADDOs that cannot sufficiently stock all the medicines on its list.

Disease Burden

To assess whether ADDOs appropriately address the needs of the communities they serve, EADSI measured the household prevalence of both acute and chronic diseases in Singida, Mara, and Ruvuma. An average of 50% of respondents reported that someone in the household in the previous two weeks had an acute illness and an average of 18% reported chronic illness. The three regions also had similar patterns for specific conditions. For acute conditions, an average of 59% reported fever; an average of 36% cough or other upper respiratory infections; and 8% with vomiting or diarrhea. An average of 98% took medicines for the acute illness. For chronic disease, the top four reported by someone in the household were: hypertension and cardiovascular disease at 27%; asthma, 14%; arthritis, 13%, and ulcers, 12%. An average of only 78% of those with a chronic condition took some sort of medication for it in the previous two weeks.

The Future of ADDOs

The map below shows the status of the program rollout in Tanzania as of November 2011. In 2009, the Ministry of Health and Social Welfare issued a notice to phase out all unaccredited drug shops by 2011—all 21 regions have at least started activities to introduce the ADDO initiative.

A new Gates Foundation-funded program, Sustainable Drug Seller Initiatives (SDSI), builds on EADSI. One of SDSI's objectives is to enhance the ADDO program's long-term maintenance and sustainability, contributions to community-based access to medicines and care, and ability to adapt to changing health needs and health system context.

ADDO Status as of November 2011
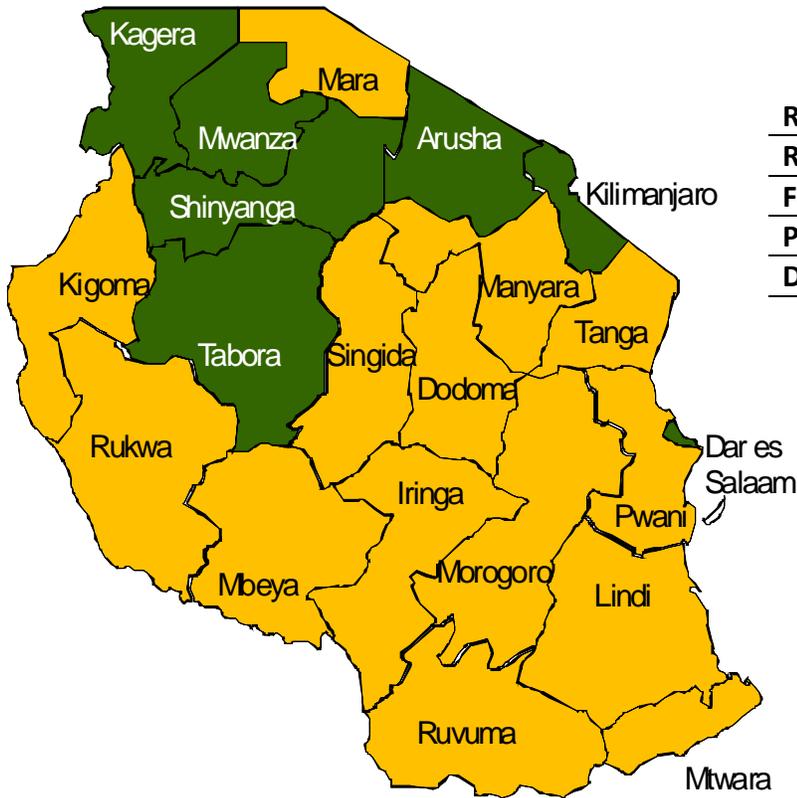
Regions completed out of 21	14
Regions in initial stages	7
Functioning ADDOs	3,484
Potential ADDOs	5,853
Dispensers trained	7,126

ADDO regions

Regions in initial stages of ADDO implementation

Creating a Sustainable Private-sector Drug Seller Program in Uganda

The East African Drug Seller Initiative (EADSI) aimed to increase access to quality medicines and pharmaceutical services in underserved areas through involvement of the private sector. Funded by the Bill & Melinda Gates Foundation through a three-year grant, EADSI built on Management Sciences for Health's (MSH) Strategies for Enhancing Access to Medicines Program, also funded by Gates and which, in collaboration with the government of Tanzania, launched the country's successful accredited drug dispensing outlet (ADDO) program. EADSI's goal was to create a sustainable accredited drug seller model that can be adapted, replicated, and scaled up in underserved regions of developing countries and that will ultimately operate independent of donor support.

Situation in Uganda: Class C drug shops are licensed by Uganda's National Drug Authority (NDA) to sell over-the-counter drug products. However, most also illegally sell prescription drugs, such as antibiotics, and many drug sellers also provide injection services. Although over 40% of the 106 drug sellers interviewed in an EADSI assessment in Mpigi and Kibaale districts in 2008 refused to answer a question about sales of prescription medicines, about 28% of those who responded said they were unaware of the medicines that they were not allowed to stock. NDA has licensed over 5,000 drug shops nationwide, but thousands more may be operating without licenses. Most shops do not use signage to identify themselves as drug sellers, which allows them to evade NDA inspectors more easily. Additional problems include inadequate storage and inventory management; poor record keeping and dispensing practices; and little supervision or oversight of shop operations.

Strategy for Change: The EADSI program worked with national and local stakeholders to develop an accreditation model based on the Tanzanian ADDOs, but adapted to the Ugandan context. NDA, the initiative's lead implementer, in collaboration with the Pharmaceutical Society of Uganda and MSH, selected two districts, Kibaale and Mpigi, to serve as the demonstration and control districts for the new initiative.

The specific objectives in developing Uganda's Accredited Drug Shop (ADS) model were to—

- Increase access to quality essential medicines, particularly in remote areas, through private sector drug sellers
- Strengthen the regulatory monitoring and inspection of drug sellers by national and local authorities
- Improve the quality of drug shop dispensing services through training, accreditation, supervision, and continuing education
- Improve the record keeping practices for medicines sold, including purchases, adverse drug reactions, referrals, and financial and sales records
- Increase drug shop sustainability through business skills training for owners and access to loans to improve premises and expand inventory
- Raise consumer awareness of the need to buy medicines from reliable sources, such as accredited drug sellers

Specific activities included stakeholder development and NDA approval of ADS standards that focus on personnel, premises, dispensing, record keeping, and a code of ethics for owners and sellers. Stakeholders also collaborated to develop training curricula for drug sellers and shop owners, a list of prescription medicines for ADS to sell legally, guidelines for a supportive supervision and inspection system, and a marketing campaign.
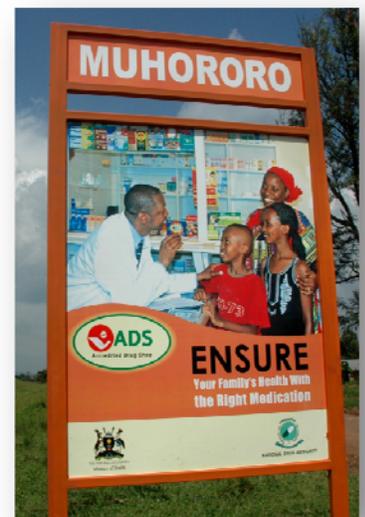
Implementation activities included conducting local sensitization meetings, mapping and inspecting the existing licensed and unlicensed drug shops, and training 246 sellers in good dispensing practices and 82 owners in business practices. In addition, local monitors and supervisory teams received training in the accreditation standards and using checklists. NDA and the local authorities collaborated to assure that ADS had and used dispensing logs, referral forms, and other record keeping and job aids. After a local media campaign to raise awareness, the ADS program was officially launched by the former Minister of Health, Dr. Stephen Mallinga, in November 2009 with a community celebration.

Program Evaluation: EADSI collected qualitative data through stakeholder interviews and focus group discussions with national and local stakeholders, including representatives from 88% of the ADS, district health officials, and central level staff from NDA, Pharmaceutical Society of Uganda, and the Ministry of Health. Data collection in Kibaale and Mpigi used mystery shoppers and shop audits. Endline data was collected in September 2010—10 months after the ADS launch. In addition, EADSI conducted baseline and endline household surveys in Kibaale and Mpigi to assess community health concerns and medicine use behavior.

Results: At baseline, Kibaale had 85 licensed Class C drug shops (and over 50 unlicensed shops); 73 (86%) of the licensed shops converted to ADS. In addition, three shops converted to full-service pharmacies, which increased access in the community. At endline, the number of licensed Class C shops had risen to 57 (the 9 licensed shops that did not convert for the pilot and 48 previously unlicensed shops that became licensed during the pilot). The increase in licensing of Class C drug shops indicated shop owners' willingness to progress toward accreditation.

Availability of antidiarrheals. The number of ADS stocking oral rehydration solution (ORS) increased 78% (from 50% at baseline to 89% at endline) and ADS stocking zinc tablets increased from 6% to 62%. The number of drug shops in the control district of Mpigi also experienced smaller increases in antidiarrheal availability (78% to 88% for ORS and 13% to 24% for zinc).

Availability of antimalarials. The chart below shows the evidence of Uganda's push to increase artemether-lumefantrine (ALU) in the private sector in both Kibaale and Mpigi. However, the significant result of accreditation in Kibaale is illustrated through the dramatic decreases in chloroquine and sulfadoxine-pyrimethamine (SP), which are no longer recommended for uncomplicated malaria treatment. Mpigi also experienced moderate reductions.

Availability of injectables. Another impressive result is the decrease in availability of injectables at ADS post-pilot. Drug shops are not authorized to sell or provide injections, and yet the baseline data in Kibaale showed that many did. The dispensing training for sellers emphasized the risks of providing injections—a message that they clearly took to heart—and coupled with monitoring and inspection, the availability of injectables in ADS was reduced to zero, while Mpigi remained unchanged.

Percentage of Class C drug shops and ADS with injectables available at baseline and endline
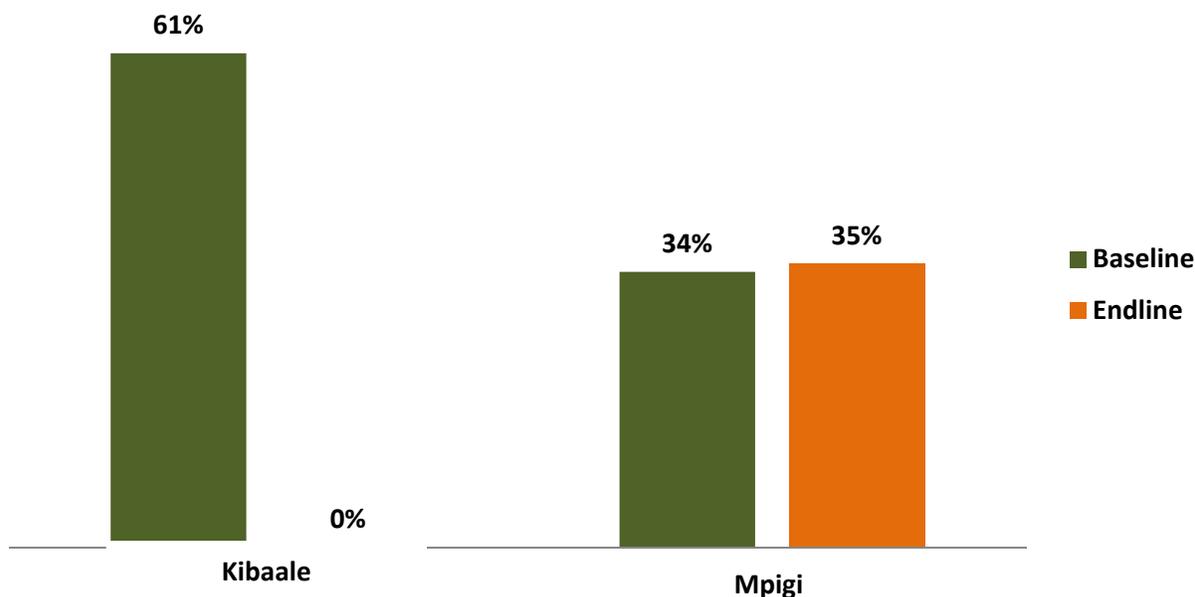
Quality of antimalarial dispensing. Using mystery shoppers, EADSI assessed how well drug sellers dispensed treatment for a simple malaria scenario in a child. The percentage of encounters with appropriate dispensing in Kibaale rose from only 6% at baseline to 68% at endline. Mpigi drug shops also experienced increases in dispensing quality, although to a lesser degree. The positive results in both districts were likely related to the country's efforts to increase the use of ALU.

Percentage of encounters with appropriate malaria treatment
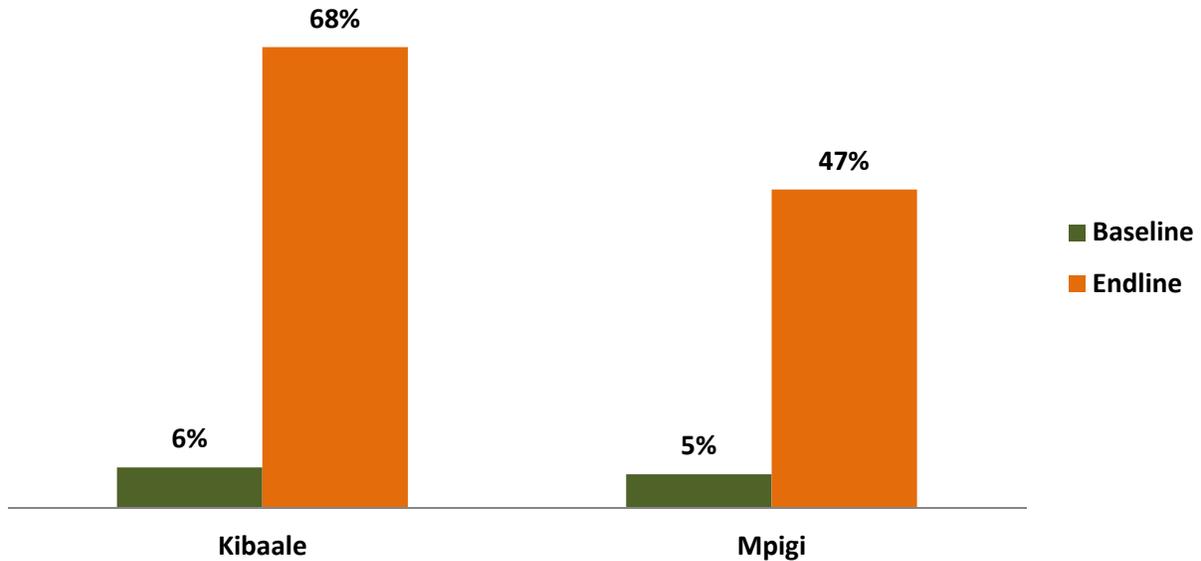
Quality of dispensing services. Dispensing service indicators generally improved after the ADS intervention; however, room for improvement should be addressed in future training. In the baseline and endline evaluations in Kibaale, the percentage of mystery shopper encounters where the drug seller—

- Asked about symptoms—rose from 56% to 64%
- Asked about other medicines the child took—increased from 31% to 64%
- Gave instructions for taking medicines—decreased from 75% to 68%

In addition, the percentage of mystery shoppers who were referred to a health facility increased in Kibaale from 6% at baseline to 15% at endline. Because ADS training should result in drug sellers feeling confident about handling uncomplicated malaria, the referral rate post-pilot should have been zero. In Mpigi, the same indicators of dispensing services either deteriorated or remained unchanged between baseline and endline.

Stakeholder perceptions: Interviews with ADS stakeholders showed general satisfaction with the accreditation concept and implementation process.

The top reason that owners cited for participating in the initiative was the expanded list of allowable drugs for sale legally. The expanded list, which includes select antibiotics, makes a previously illicit activity acceptable. "We no longer have to run away when the inspectors come because we are now allowed to have antibiotics," said an owner from Muhorro village.

Sellers most appreciated increasing their skills to deliver quality services and therefore their social status. A seller from Buronzi village said, "They now refer to us as *abasawo batufu* [true doctor] because we now know what we do, and we are held with high esteem in society."

Kibaale drug shop before…   **…and after ADS conversion**

ADS owners paid an average of 700,000 Ugandan shillings (~268 U.S. dollars) to renovate their shops to meet accreditation standards. Ninety percent of the owners interviewed felt the cost was worth the investment.

"The customers have now increased; they see the business clean and organized, and we even have most of the medicines they want" —ADS seller in Kasimbi village.

All the shop owners and sellers (n = 64) who were interviewed liked to have inspectors come to their shops saying that they "give us advice that is helpful to the business." This attitude was an abrupt turn-around from what had reportedly been a contentious relationship: "I don't mind NDA or district inspectors. NDA used to be very hostile to us; it's now like eating on the same plate with a lion. They are all very supportive"—ADS owner from Kagadi.

In the community, close to 100% of households surveyed in Kibaale and Mpigi reported that they routinely buy medicines at Class C drug shops or ADS. At baseline, 10% of households in Kibaale reported that drugs shops were their first choice of where to access health care. By endline, that percentage had increased by 160% to 23%. In Mpigi, those who responded "drug shops" increased from 12 to 15%.

Challenges: Stakeholders, particularly shop owners and dispensers, were generally enthusiastic about the initiative, but challenges remain—

- Most shop owners rent their premises (78% of those interviewed). Convincing property owners to do major renovations is difficult. Some shops have been forced to relocate.
- Financial institutions focus on other sectors (e.g., agriculture), so getting a loan is harder for drug sellers; however, 100% (n = 64) of the owners interviewed said they faced no challenges to meeting the accreditation standards.
- Customers still want medicines outside the list.
- Customers still demand half doses and unapproved medicines.
- ADS face competition from illegal (unlicensed) sellers.
- More sellers need to be trained, so they can fill openings caused by attrition and the accreditation of new shops.

"When the people come to an ADS outlet, they are told what to do. They ask for some unapproved medicine and the sellers refuse to give it to them after explaining why. But they go to the next drug shop (nonaccredited) and get the medicine there'' –ADS owner from Kasamba.

"The jingle that was broadcast on the radio needs to be changed because already people know about ADS, they now need to be told about how to use the medicines and to listen to what the ADS sellers tell them" —ADS seller in Karuguuza.

The Future of ADS. In August 2011, additional training will be held for about 60 dispensers who will work at the 34 ADS that are awaiting accreditation and at existing shops that need additional dispensers. The new accreditations will bring the total number of ADS to over 100 in Kibaale district.

EADSI commissioned a business and profitability analysis from a consultant who reviewed the ADS business model and made recommendations for how the model can be strengthened to assure sustainability. Recommendations included broadening the type of products that ADS offer (such as cosmetics) to reduce strict reliance on medicine sales; participating in community health and welfare initiatives; and becoming involved with health insurance schemes, if they are available in the community.

NDA budgeted for sensitization and supportive supervision activities for Kibaale, and local authorities in Kibaale are planning to continue the initiative. For example, the Kibaale Secretary of Health said about the ADS initiative, "ADS is very good, we are now budgeting for it in our integral activities for health. We pay staff to do support supervision for ADS, which we used not to do. We also facilitate by giving them transport. Even in our sensitization and mobilization activities, ADS is now included. If you look at our meeting minutes notes you can see ADS featured strongly. ADS has really helped our people supplement the government in provision of quality health services. We are proud of it and I am extremely satisfied with the ADS implementation in Kibaale."

A new Gates Foundation-funded program, Sustainable Drug Seller Initiatives (SDSI), builds on EADSI. One of SDSI's objectives is to enhance the ADS program's long-term sustainability, contributions to community-based access to medicines and care, and ability to adapt to changing health needs and health system context.

Annex 2: Monitoring & Evaluation Frameworks

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EAST AFRICA DRUG SELLER INITIATIVE (EADSI)
Monitoring & Evaluation Framework
TANZANIA

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DIMENSION	VARIABLES	INDICATORS	METHODOLOGY
SCALABILITY: Ability to expand an intervention to support larger system without impacting performance (as measured in Accessibility dimension)	Quality of pharmaceutical products	% of items sampled that are registered with the TFDA	Drug shop data collection in Singida and Mara regions • 30 randomly selected shops in each region • Data on quality of pharmaceutical products, product affordability, and product availability collected on 30 tracer drugs using availability and price data collection tool based on SEAM and HAI methodologies
	Product affordability	Average % difference in median price to patients between ADDOs/DLDBs and international reference prices for a set of tracer items (prescription and nonprescription medicines)	
	Product availability	% of a set of tracer items in stock	
	Quality of pharmaceutical services—malaria	% of encounters in which appropriate first-line antimalarial medicine was sold for malaria treatment % of encounters in which appropriate first-line antimalarial medicine was dispensed consistently with standard treatment guidelines (STGs) for malaria treatment % of encounters in which attendant provided instructions on how to take the medication % of encounters in which attendant asked about the symptoms of the child % of encounters in which attendant asked about any medications the child may have taken % of encounters in which the attendant asked about general danger signs in children under 5[18]	Mystery shopper visits to select DLDB in Mara and ADDOs in Singida[19] to determine quality of pharmaceutical services for malaria and childhood diarrhea • 60 randomly selected shops for each disease scenario in each region (120 shops per region total)

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[18] Danger signs are refusal/inability to drink or breastfeed, vomiting, lethargy, convulsions, unconsciousness
[19] Singida region (implementation using revised model) compared with Mara region that is not on the initial ADDO rollout list (naïve)

DIMENSION	VARIABLES	INDICATORS	METHODOLOGY
	Quality of pharmaceutical services—childhood diarrhea	% of encounters in which an antibiotic was sold for treatment of non-bloody diarrhea in children under 5 years % of encounters in which attendant provided instructions on how to take the medication % of encounters in which attendant asked about the symptoms of the child % of encounters in which attendant asked about any medications the child may have taken % of encounters in which the attendant provides advice on danger signs in children under 5	
	Stakeholder satisfaction with decentralized ADDO implementation process	% of stakeholders who express satisfaction with ADDO implementation process	Stakeholder interviews (Singida only) • ADDO owners • ADDO dispensers • Local authorities • Central government authorities
	Consumer satisfaction	% of households that obtain most of their medicines from drug shops % of households whose perception is that drug shop attendants are knowledgeable about medicines % of households whose perception is that medicines from drug shops are affordable % of households that choose a drug shop as first choice facility for advice % of households that choose drug shops as first choice facility to obtain medicines % of households that routinely obtain medicines from the same facility	Limited household survey based on adapted WHO methodology to determine satisfaction indicators and common health concerns (Singida and Mara) • 300 households in each region • Households sampled based on 30 randomly chosen shops used in the price/availability data collection then stratified by density of shops in district • First 10 households chosen by walking in a straight line from the shop

DIMENSION	VARIABLES	INDICATORS	METHODOLOGY
		% of households that have the money to buy the medicines they need	
		% of households that report they can buy drugs on credit from the drug shop	
	Disease burden	Prevalence of specific acute disease conditions (e.g., malaria) in previous two weeks	
		Prevalence of chronic disease conditions (e.g., asthma)	
		% of people in household with acute or chronic conditions that sought health care in previous two weeks	
		% of households where someone reported an acute condition that took medicines in previous two weeks for the specific acute condition (e.g., malaria)?	
		% of households where someone reported a chronic condition that took medicines in previous two weeks for the specific chronic condition (e.g., asthma)?	
		Average cost to treat specific acute disease condition	
		Average cost of managing specific chronic disease condition for previous month	
	Availability of resources and commitment at district level	% local government units with budget allocations to implement ADDO program	Review of program records in **Mtwara** and **Singida**[20]
	Time required for implementation (geographically defined) (ADDO conversion time)	Time required to implement ADDO program in a region (Mtwara vs. Singida)	

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[20] Mtwara region (ADDOs implemented using original implementation approach by GoT in 2007) compared with Singida region (intervention using revised implementation model)

DIMENSION	VARIABLES	INDICATORS	METHODOLOGY
	Stakeholder satisfaction with decentralized ADDO implementation process	% of stakeholders who express satisfaction with implementation process	Stakeholder interviews in **Mtwara** and **Singida** • Owners • Dispensers • National government authorities Local government authorities
	Program implementation cost	Cost of establishing an ADDO program in a region (Mtwara vs. Singida)	Researching ADDO program cost elements based on project records (**Mtwara**, **Singida**, and **central level**): • Advocacy and sensitization • Marketing • Mapping and preliminary inspection • Financing • Training (business and dispensing) • Accreditation and final inspection • Supervision
SUSTAINABILITY: Persistence of the intervention's effects over time	Wholesale supply channel	% ADDOs within a 2-hour drive of an ADDO-restricted wholesaler	Indicators measured in regions/districts with more than two years of implementation (**Ruvuma** and **Mtwara**) Review Government of Tanzania (GoT) and Tanzania Food and Drugs Authority (TFDA) documents on ADDO implementation and operations
	Financial success for ADDOs	% ADDOs that are in operation > two years	Measure business plan/financial indicators in **Ruvuma** and **Mtwara**
	Institutionalization • Legal and regulatory framework • Organizational structure(s)/ implementation "unit" • Operational funding • Human resource development	Changes in legislation and regulation that allow expanded ADDO services (e.g., updated drug lists) GoT central entity formally mandated/ responsible/ established for ADDO program implementation/technical support to local governments % zones with ADDO rollout areas with (established/defined) training sites % district health authorities budgeting for ADDO inspections	Measure program-specific indicators at the national level and in regions/districts with more than two years of implementation (**Ruvuma** and **Mtwara**) Review GoT and TFDA documents on ADDO implementation and operations Stakeholder interviews • ADDO owners • ADDO dispensers • Local authorities • Central government authorities

DIMENSION	VARIABLES	INDICATORS	METHODOLOGY
		% ADDO rollout districts making available at least one ADDO training course to support ADDO implementation	
	Quality of pharmaceutical products	% of items sampled that are registered with the TFDA	Collect drug shop data in **Ruvuma** region as a follow-up to SEAM baseline/endline data collection[21] • 30 randomly selected shops • Data on quality of pharmaceutical products, product affordability, and product availability collected on 30 tracer drugs using availability and price data collection tool based on SEAM and HAI methodologies [NOTE—This same information has been collected for **Mtwara** for informational purposes.]
	Product affordability	Average % difference in median price to patients between ADDOs and international reference prices for a set of tracer items (prescription and nonprescription medicines)	
	Product availability	% of a set of tracer items in stock	
	Quality of pharmaceutical services—malaria	% of encounters in which appropriate first-line antimalarial medicine was sold for malaria treatment % of encounters in which appropriate first-line antimalarial medicine was dispensed consistently with standard treatment guidelines (STGs) for malaria treatment % of encounters in which attendant provided instructions on how to take the medication % of encounters in which attendant asked about the symptoms of the child % of encounters in which attendant asked about any medications the	Conduct mystery shopper visits to select ADDOs in **Ruvuma** to determine quality of pharmaceutical services for malaria and childhood diarrhea • 60 randomly selected shops for each disease scenario (120 shops total in Ruvuma)

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[21] To enable comparisons with SEAM results these indicators may need to change to those used during SEAM

DIMENSION	VARIABLES	INDICATORS	METHODOLOGY
		child may have taken % of encounters in which the attendant asked about general danger signs in children under 5[22]	
	Quality of pharmaceutical services—childhood diarrhea	% of encounters in which an antibiotic was sold for treatment of non-bloody diarrhea in children under 5 years % of encounters in which attendant provided instructions on how to take the medication % of encounters in which attendant asked about the symptoms of the child % of encounters in which attendant asked about any medications the child may have taken % of encounters in which the attendant provides advice on danger signs in children under 5	
	Consumer satisfaction	% of households that obtain most of their medicines from drug shops % of households whose perception is that drug shop attendants are knowledgeable about medicines % of households whose perception is that medicines from drug shops are affordable % of households that choose a drug shop as first choice facility for advice % of households that choose drug shops as first choice	Limited household survey in **Ruvuma** based on adapted WHO methodology to determine satisfaction indicators and common health concerns • 300 households • Households sampled based on 30 randomly chosen shops used in the price/availability data collection then stratified by density of shops in district • First 10 households chosen by walking in a straight line from the shop

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[22] Danger signs are refusal/inability to drink or breastfeed, vomiting, lethargy, convulsions, unconsciousness

DIMENSION	VARIABLES	INDICATORS	METHODOLOGY
		facility to obtain medicines % of households that routinely obtain medicines from the same facility % of households that have the money to buy the medicines they need % of households that report they can buy drugs on credit from the drug shop	
	Disease burden	Prevalence of specific acute disease conditions (e.g., malaria) in previous two weeks Prevalence of chronic disease conditions (e.g., asthma) % of people in household with acute or chronic conditions that sought health care in previous two weeks % of households where someone reported an acute condition that took medicines in previous two weeks for the specific acute condition (e.g., malaria)? % of households where someone reported a chronic condition that took medicines in previous two weeks for the specific chronic condition (e.g., asthma)? Average cost to treat specific acute disease condition Average cost of managing specific chronic disease condition for previous month	Limited household survey in **Ruvuma** based on adapted WHO methodology to determine satisfaction indicators and common health concerns • 300 households • Households sampled based on 30 randomly chosen shops used in the price/availability data collection then stratified by density of shops in district • First 10 households chosen by walking in a straight line from the shop

The Accredited Drug Dispensing Outlet (ADDO)/*Duka la Dawa Muhimu* Model

MODEL/CHANGES	ORIGINAL SEAM TANZANIA	REVISED SEAM TANZANIA
BUSINESS MODEL [NO CHANGES]	Retail sales of— • Part II medicines (non-prescription, symptom remedies, vitamins, e.g., oral contraceptives, paracetamol, folic acid, ferrous sulfate, vitamin A) • Selected Part I medicines (antibiotics, antimalarials, and selected prescription medicines, e.g., co-trimoxazole, diclofenac, metronidazole, sulfadoxine/pyrimethamine, amoxicillin, erythromycin, benzylpenicillin injection, doxycycline, nystatin oral suspension) • Other health and non-health related commodities optional Infrastructure and equipment must meet minimum standards Out-of-pocket and third-party (e.g., insurance scheme) payments Shopkeeper access to micro-financing sources, as appropriate (e.g., MEDA, National Micro-Finance Bank, Rural Savings and Credit Co-operatives, others?)	Retail sales of— • Part II medicines (non-prescription, symptom remedies) • Selected Part I medicines (antibiotics, antimalarials, and selected prescription medicines, e.g., co-trimoxazole, diclofenac, metronidazole, sulfadoxine/pyrimethamine, ACT fixed-dose products, amoxicillin, erythromycin, benzylpenicillin injection, doxycycline, nystatin oral suspension) • Other health and non-health related commodities optional Infrastructure and equipment must meet minimum standards [no change in standards] Out-of-pocket and third-party (e.g., insurance scheme) payments Shopkeeper access to micro-financing sources (local sources, (e.g., National Micro-Finance Bank, Rural Savings and Credit Co-operatives, others?)
TRAINING MODEL **[CHANGES in duration of dispenser training, training responsibility and training location]**	Training program content: • medicines management • retail business management Training duration: • 40 days (dispensers) • 6 days (shop owners) Training institution(s): • Tanzania Food and Drug Authority (TFDA) and Management Sciences for Health (MSH/SEAM) • MEDA (business operations and related topics)	Training program content: • medicines management • retail business management Training duration: • 30 days (dispensers) • 6 days (shop owners) Training institutions(s): • District Health Team coordinates training courses that are conducted by pool of trained trainers at local training sites
MONITORING AND SUPERVISION (enforcement of standards) [CHANGES in responsibilities]	TFDA responsible at national level District Council responsible at local level Ward inspectors	Ministry of Health/TFDA responsible at national level for inspections Pharmacy Council responsible for (standard-setting and) supervision-National District Council responsible for inspections CFDC (monitoring) District councils responsible for supervision -CHMT

MODEL/CHANGES	ORIGINAL SEAM TANZANIA		REVISED SEAM TANZANIA	
PROGRAM FINANCING SOURCES	SEAM/BMGF (technical assistance) (2001-2005) USAID (technical assistance) (2005-2008)[Morogoro] Government of Tanzania (TFDA) [Mtwara, Rukwa]		EADSI/BMGF (technical assistance to revise model; evaluation of revised implementation model) (2007–2010) GFATM Round 7 to Government of Tanzania (rollout to six additional regions) Danida grant to GoT (rollout) Rockefeller Foundation (role of ADDO associations and strategy for their development) (2009)	
GEOGRAPHIC IMPLEMENTATION	Pilot in: 1. Ruvuma (Control in Singida)	Roll out in: 2. Morogoro 3. Mtwara 4. Rukwa	Roll out in: 1. Kigoma 2. Lindi 3. Mbeya 4. Pwani 5. Singida 6. Tanga	Sensitization activities (no funds for implementation): 1. Arusha 2. Dodoma 3. Iringa 4. Kagera 5. Kilimanjaro 6. Manyara 7. Mara 8. Mwenza 9. Shinyanga 10. Tabora

EAST AFRICA DRUG SELLER INITIATIVE (EADSI)
Monitoring & Evaluation Framework
UGANDA

DIMENSION	VARIABLES	INDICATORS	METHODOLOGY
TRANSFERABILITY: Extent to which an intervention can be replicated and implemented in new country	Quality of pharmaceutical products	% of items sampled that are registered with the NDA	Drug shop data collection in **Kibaale** and **Mpigi** districts • For baseline data collection, 30 randomly selected Class C drug shops in each district • For endline data collection, 30 randomly selected Accredited Drug Shops in Kibaale and 30 randomly selected Class C shops in Mpigi • Data on quality of pharmaceutical products, product affordability, and product availability collected on 30 tracer drugs using availability and price data collection tool based on SEAM and HAI methodologies
	Product affordability	Average % difference in median price to patients between ADS/Class C drug shops and international reference prices for a set of tracer items (prescription and nonprescription medicines)	
	Product availability	% of a set of tracer items in stock	
	Quality of pharmaceutical services—malaria	% of encounters in which appropriate first-line antimalarial medicine was sold for malaria treatment % of encounters in which appropriate first-line antimalarial medicine was dispensed consistently with standard treatment guidelines (STGs) for malaria treatment % of encounters in which attendant provided instructions on how to take the medication % of encounters in which attendant asked about the symptoms of the child % of encounters in which attendant asked about any medications the child may have taken	• Mystery shopper visits in **Kibaale** and **Mpigi** to determine quality of pharmaceutical services for malaria 60 randomly selected shops in each district

DIMENSION	VARIABLES	INDICATORS	METHODOLOGY
		% of encounters in which the attendant asked about general danger signs in children under 5[23]	
	Consumer satisfaction	% of households that obtain most of their medicines from drug shops % of households whose perception is that drug shop attendants are knowledgeable about medicines % of households whose perception is that medicines from drug shops are affordable % of households that choose a drug shop as first choice facility for advice % of households that choose drug shops as first choice facility to obtain medicines % of households that routinely obtain medicines from the same facility % of households that have the money to buy the medicines they need % of households that report they can buy drugs on credit from the drug shop	Limited household survey in **Kibaale** and **Mpigi** based on adapted WHO methodology to determine satisfaction indicators and common health concerns • 300 households in each district • Households sampled based on 30 randomly chosen shops used in the price/availability data collection then stratified by density of shops in district • First 10 households chosen by walking in a straight line from the shop
	Disease burden	Prevalence of specific acute disease conditions (e.g., malaria) in previous two weeks Prevalence of chronic disease conditions (e.g., asthma) % of people in household with acute or chronic conditions that sought health care in previous two weeks	

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[23] Danger signs are refusal/inability to drink or breastfeed, vomiting, lethargy, convulsions, unconsciousness

DIMENSION	VARIABLES	INDICATORS	METHODOLOGY
		% of households where someone reported an acute condition that took medicines in previous two weeks for the specific acute condition (e.g., malaria)? % of households where someone reported a chronic condition that took medicines in previous two weeks for the specific chronic condition (e.g., asthma)? Average cost to treat specific acute disease condition Average cost of managing specific chronic disease condition for previous month	

DIMENSION	VARIABLES	INDICATORS	METHODOLOGY
	Stakeholder acceptance • Drug shop owners • Customers	% Class C drug shops converting to ADS or ADS as % of Uganda drug shops % of households that obtain most of their medicines from drug shops % of households whose perception is that drug shop attendants are knowledgeable about medicines % of households whose perception is that medicines from drug shops are affordable % of households that choose a drug shop as first choice facility for advice % of households that choose drug shops as first choice facility to obtain medicines % of households that routinely obtain medicines from the same facility % of households that have the money to buy the medicines they need % of households that report they can buy drugs on credit from the drug shop	Stakeholder interviews in EADSI's demonstration district in **Kibaale** and at **central level** • Government of Uganda authorities • Ministry of Health authorities • Pharmacy association/ professionals • Local health authorities • Retail outlet owners • Pharmaceutical wholesalers • Consumers/clients Review ADS licensing registers and records in Uganda Utilize data from household surveys in **Kibaale** Review program documents on ADS implementation and operations in Uganda

Annex 3: Tracer Items for Availability and Price Survey

1. Albendazole tablet 200mg
2. Amoxicillin capsule, 250mg
3. Amoxicillin suspension, 125mg/5ml
4. Artemether Lumefantrine tablet 20/120 mg
5. Aspirin (Acetyl Salicylic acid) tablet, 300mg
6. Benzoic/ Salicylic acid ointment
7. Benzyl Penicillin injection 5MUs
8. Cotrimoxazole tablet 480mg
9. Cotrimoxazole suspension 240mg/5ml
10. Doxycycline capsule/tab 100mg
11. Erythromycin tablet 250mg
12. Erythromycin susp 125mg/5ml 250mg
13. Ketoconazole tablet 200mg
14. Mebendazole tablet 100mg
15. Metronidazole tablet 200mg
16. Metronidazole susp 200mg/5ml
17. Nystatin suspension 100,000 iu
18. Nystatin pessary 100,000 iu
19. ORS
20. Paracetamol tablet 500mg
21. Procaine Penicillin Fortified 4MU
22. Quinine injection 300mg/ml
23. Sulfadoxine +Pyrimethamine tablet 525 mg
24. Sulfametopyrazine+Pyrimethamine tablet 525mg
25. Tetracycline eye ointment 1%, 3.5g
26. Zinc tablet 20mg
27. Condoms
28. Combined contraceptive pill
29. Glucose infusion 5%
30. Sodium chloride infusion 0.9%

Availability and Price Form

This form is used for the indicators listed below:

- Average % of tracer list items in stock
- Average % difference in price to patients between health facilities in Ruvuma and Mtwara regions for a list of tracer items selected
- Average number of days that a salaried worker needs to work in order to pay for a standard treatment of tracer conditions
- Average number of days that a resident of Ruvuma and Mtwara needs to work in order to pay for a standard treatment of tracer conditions.

Important: *the medicines and supplies on the list are Primary health care medicines and the list has been generated basing on the Essential medicines list 2007.*

Data Summary:

Where to Go	Whom to Ask	What to Get
ALL FACILITIES	Inform the attendant of the purpose of the survey and obtain permission to collect the data. This should be done after the simulated client exercise has been conducted. Explain that a small fee will be paid to them for their assistance.	Ask to see the items on the list that are in stock. Note the pack sizes and prices for the cheapest and most expensive brands.

Instructions for completing the forms:

1. Introduce yourself to the attendant at the shop and explain the purpose of your visit. You may wish to present the letter of introduction or authorization to conduct the survey.
2. **Name and location of the ADDO**: Explain that the information that will be gathered will be kept confidential. The name of the shop and location will be used only for reference only.
3. **Availability.** Ask the attendant to show you the drugs on the list, one by one. You may offer various name brands if the generic names are not known. When you have seen the item and determined that it is not expired, check that it is available.
4. **Cheapest and Most Expensive Prices:** Ask the attendant to see the most expensive brand of the product, and the least expensive brand. Note the number of units in the pack and the pack price.

Use this form to collect information on stock availability and prices.

Name of Drug and Location of ADDO
_____

Note: *If product is sold by individual units (e.g., tablet) rather than packs, note unit price and mark "1" for number of units per pack.*

Generic name, dosage form, strength	Medicine Type	Brand name(s)	Manufacturer/Registration	Available Y/N	No. of units per pack	Price of pack found	Unit price	Expired Y, N, DK
Albendazole tablet 200mg	Lowest Price							
	Highest price							
Amoxicillin capsule, 250mg	Lowest Price							
	Highest price							
Amoxicillin	Lowest Price							

suspension, 125mg/5ml	Highest price							
Artemether Lumefantrine tablet 20/120 mg	Lowest Price							
	Highest price							
Aspirin (Acetyl Salicylic acid) tablet, 300mg	Lowest Price							
	Highest price							
Benzoic/ Salicylic acid ointment	Lowest Price							
	Highest price							
Benzyl Penicillin injection 5MUs	Lowest Price							
	Highest price							
Cotrimoxazole tablet 480mg	Lowest Price							
	Highest price							
Cotrimoxazole suspension 240mg/5ml	Lowest Price							
	Highest price							
Doxycycline capsule/tab 100mg	Lowest Price							
	Highest price							
Erythromycin tablet 250mg	Lowest Price							
	Highest price							
Erythromycin susp 125mg/5ml 250mg	Lowest Price							
	Highest price							
Ketoconazole tablet 200mg	Lowest Price							
	Highest price							
Mebendazole tablet 100mg	Lowest Price							
	Highest price							
Metronidazole tablet 200mg	Lowest Price							
	Highest price							
Metronidazole susp 200mg/5ml	Lowest Price							
	Highest price							
Nystatin suspension 100,000 iu	Lowest Price							
	Highest price							
Nystatin pessary 100,000 iu	Lowest Price							
	Highest price							
ORS	Lowest Price							
	Highest price							
Paracetamol	Lowest Price							

tablet 500mg	Highest price							
Procaine Penicillin Fortified 4MU	Lowest Price							
	Highest price							
Quinine injection 300mg/ml	Lowest Price							
	Highest price							
Sulfadoxine + Pyrimethamine tablet 525 mg	Lowest Price							
	Highest price							
Sulfametopyrazine +Pyrimethamine tablet 525mg	Lowest Price							
	Highest price							
Tetracycline eye ointment 1%, 3.5g	Lowest Price							
	Highest price							
Zinc tablet 30mg	Lowest Price							
	Highest price							
Condoms	Lowest Price							
	Highest price							
Combined contraceptive pill	Lowest Price							
	Highest price							
Glucose infusion 5%	Lowest Price							
	Highest price							
Sodium chloride infusion 0.9%	Lowest Price							
	Highest price							

Instructions for Data Collector

Scenario for Simulated Client 1: *Uncomplicated Malaria*

Present yourself as the caregiver of a 5 year-old child who has had a fever on and off for a week. Use local terms to describe the symptoms of the child. The child may be a boy or a girl. Ask which products to give the child. *Do not provide any additional information unless the drug seller directly asks you for more information.* Purchase the drugs recommended by the retail drug seller and leave the shop.

If the drug seller asks these questions, reply as follows:

> **The symptoms of the child:** In addition to the fever, the child has complained of a headache and aches and pains since last week. She or he has been feeling generally unwell for a week.

> **If the child took medication:** Say that he or she took some Panadol a week ago. The fever went away after this, but returned three days later.

> **Can the child take food and/or liquids:** Say he or she is able to take both liquids and food.

Actions

Notice and remember the following:

1. What are the name(s) of the product(s) that you purchased?
2. Did the drug seller ask about the child's symptoms?
3. Did the drug seller ask about what other medications the child took?
4. Did the drug seller tell you how to give the child the medication (how much and when and for how long)?
5. Did the drug seller provide any advice on watching out for danger signs in the child (refusal to eat/drink or breastfeed, vomiting, convulsion, lethargy, unconsciousness)?

Indicators

The case scenario is used to collect the indicators below:

- % of encounters in which appropriate first-line antimalarial medicine was sold for malaria treatment
- % of encounters in which appropriate first-line antimalarial medicine was dispensed consistently with standard treatment guidelines (STGs) for treatment of malaria
- % of encounters in which attendant provided instructions on how to take the medication
- % of encounters in which attendant asked about the symptoms of the child
- % encounters where attendant asked for more information about the condition presented e.g. ask age of child, duration of fever, danger signs, and previous treatment.
- % of dispensers who warned caregivers about any signs of progressive illness
- % of dispensers who recommended a referral visit to a doctor or clinic if the signs appear
- % of dispensers who prescribed an ineffective antimalarial (one which is no longer recommended)
- Cost of the medicines.

Background

The simulated client case is based on the National Guidelines for malaria diagnosis and treatment in Tanzania. The client is a parent/relative of a 6 year old child with classic symptoms of uncomplicated malaria. The ideal scenario would be for the shop keeper to ask the client questions about the symptoms and medication history. On the basis of this, the attendant may refer the parent/ relative to a health care professional or may recommend ACTs or S/P in doses appropriate for a 6 year old child. No antibiotics or injections of any kind are indicated.

Data Summary:

Where to Go	Whom to Ask	What to Get
ADDOs	Data collection is done as a simulation. Shop managers/dispensers should be unaware of the process so no permission is needed.	Determine the prescribing practices in ADDOs for a case of uncomplicated malaria for a child Determine the cost of treatment as prescribed in the ADDOs.

*The data collection form should be completed immediately **after** the simulated client.* Doing so will facilitate remembering the interactions during the purchase. It will also help ensure that the attendants do not realize that they are being evaluated.

Specific information to look for:

Which drugs were recommended for purchase by the drug seller?

Record information on each drug recommended for purchase during the simulated purchase encounter.

1. **Name, Strength, and Dosage Form:** Write the name, strength, and dosage form of each purchased drug. Write the name of the drug that the retail drug seller gives, for example, SP (generic name) or Orodar (commercial name). Also, write in the strength of the drug prescribed by the drug seller, for example, 500/25mg. If strength is not available, write *N/A* (*not available*) after the name of the medication. Write the dosage form of the prescribed drug, for example, tablet, liquid, ampoule, vial, etc. If the drug seller does not mention dosage form, write *N/A* (*not available*). Use a new row for each drug purchased. An example of a complete record is Fansidar 500mg/25mg tablet.
2. **Total Quantity:** For the quantity or unit of each drug purchased, write exactly what the drug seller dispensed. For example, 5 ml, 1 tablet, etc. Use a new row for each drug.
3. **Dosage Quantity**: For each drug purchased write the number of units the drug seller to take at one time. If the drug seller does not provide this information write *N/A* (*not available*) in *Column 3*. Use a new row for each drug.
4. **Frequency**: For each drug purchased, write the number of times a day that the drug seller told you the dose was to be taken, for example, once a day, twice a day, three times a day, etc. If frequency is not mentioned, write *N/A* (*not available*) in *Column 4*. Use a new row for each drug.
5. **Duration of Treatment (days):** Write the number of days the purchased drug is to be taken for a full course of treatment. Write exactly what the drug seller says. The duration could be expressed as 3 days, 7 days, etc. If duration is not mentioned, write *N/A* (*not available*) in *Column 4*. Use a new row for each drug.
6. **How to take (administration):** For how to take the drug, write exactly what the drug seller tells you. Administration can be expressed as after meals, with water, etc. If instructions are not mentioned by the drug seller, write *N/A* (*not available*) in *Column 5*.
7. **Price Paid:** For each drug sold by the drug seller, record the total price paid for the drug.

Simulated Client Form for Uncomplicated Malaria in ADDOs

Name of ADDO: _____ Location: _____

Name of Data collector: _____ Date of visit: _____

1. For all drugs sold to the client, write the following information.

Name	Strength	Dosage Form	Total Quantity	Dosage quantity	Frequency	Duration of Treatment *(days)*	How to Take	Price Paid
Col. 1			Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7
E.g. Fansidar	525mg	Tab	2 tablets	2 tablets	once	1 day	with food	500

2. What drugs were recommended by the drug seller but not purchased?

    a. _____   **b.** _____   **c.** _____

3. Did the drug seller ask about the symptoms of the child?   **Yes** ☐ **No** ☐

4. Did the drug seller ask about any other medicines the child may have taken?   **Yes** ☐ **No** ☐

5. Did the drug seller give instructions on how to take the medications?   **Yes** ☐ **No** ☐

6. Did the drug seller give information on how to look for danger signs?   **Yes** ☐ **No** ☐

7. Did the drug seller recommend immediate referral to a doctor or clinic?   **Yes** ☐ **No** ☐

8. Did the drug seller recommend referral to a doctor or clinic if danger signs arose   **Yes** ☐ **No** ☐

9. Did the drug seller recommend returning if symptoms did not get better?   **Yes** ☐ **No** ☐

Instructions for Simulated Clients/Data Collectors

Scenario for Simulated Client 2: Uncomplicated childhood Diarrhea

Present yourself as the caregiver of a 6 year-old child who has had diarrhea for over 6 hours. Use local terms to describe the symptoms of the child. The child may be a boy or a girl. Ask which products to give the child. *Do not provide any additional information unless the drug seller directly asks you for more information.* Purchase the drugs recommended by the retail drug seller and leave the shop.

If the drug seller asks these questions, reply as follows:

The symptoms of the child: In addition to the fever, the child has vomited three times.

If the child took medication: Say that he or she took some Panadol earlier that day.

Can the child take food and/or liquids: Say he or she is able to take both liquids and food.

Is there blood in the stool or are the stools black? Say no

Is the diarrhea accompanied by fever? Say he or she has a very mild fever

Does your child have diarrhea and signs of mild to moderate dehydration? Say the child is getting mildly dehydrated

Actions

Notice and remember the following:

6. What are the name(s) of the product(s) that you purchased?
7. Did the drug seller ask about the child's symptoms?
8. Did the drug seller ask about what other medications the child took?
9. Did the drug seller tell you how to give the child the medication (how much and when and for how long)?
10. Did the drug seller provide any advice on watching out for danger signs in the child (bloody diarrhea, dehydration, general malaise, fever)

Indicators

The case scenario is used to collect the indicators below:

- % of encounters in which ORS was sold for diarrhea
- % of encounters in which management of diarrhea was consistently with standard treatment guidelines (STGs) for the management of diarrhea
- % of encounters in which attendant provided instructions on how to take the medication (or ORS)
- % of encounters in which attendant asked about the symptoms of the child
- % encounters where attendant asked for more information about the condition presented e.g. ask age of child, fever, dehydration, danger signs, and previous treatment.
- % of dispensers who told caregivers about any signs of progressive illness
- % of dispensers who recommended a referral visit to a doctor or clinic if the signs appear.
- % of dispensers who prescribed an inappropriate product for the management of diarrhea.
- Cost of medicines

Background

The simulated client case is based on the National Guidelines for management of simple diarrhea in Tanzania. The client is a parent/relative of a 6 year old child with classic symptoms of uncomplicated diarrhea. The ideal scenario would be for the shop keeper to ask the client questions about the symptoms and medication history. On the basis of this, the attendant may refer the parent/ relative to a health care professional or may recommend ORS in doses appropriate for a 6 year old child. No antibiotics or injections of any kind are indicated.

Data Summary:

Where to Go	Whom to Ask	What to Get
ADDOs	Data collection is done as a simulation. Shop managers/dispensers should be unaware of the process so no permission is needed.	Determine the prescribing practices in ADDOs for a case of uncomplicated diarrhea. Determine the cost of treatment as prescribed in the ADDOs.

*The data collection form should be completed immediately **after** the simulated client.* Doing so will facilitate remembering the interactions during the purchase. It will also help ensure that the attendants do not realize that they are being evaluated.

Specific information to look for:

Which drugs were recommended for purchase by the drug seller?

Record information on each drug recommended for purchase during the simulated purchase encounter.

1. **Name, Strength, and Dosage Form:** Write the name, strength, and dosage form of each purchased drug. Write the name of the drug that the retail drug seller gives, for example, loperamide (generic name) or Imodium (commercial name). Also, write in the strength of the drug prescribed by the drug seller, for example, 2mg. If strength is not available, write *N/A* (*not available*) after the name of the medication. Write the dosage form of the prescribed drug, for example, tablet, liquid, ampoule, vial, etc. If the drug seller does not mention dosage form, write *N/A* (*not available*). Use a new row for each drug purchased. An example of a complete record is loperamide 2mg tablets.
2. **Total Quantity:** For the quantity or unit of each drug purchased, write exactly what the drug seller dispensed. For example, 5 ml, 1 tablet, etc. Use a new row for each drug.
3. **Dosage Quantity**: For each drug purchased write the number of units to be taken at one time. If this is not mentioned, write *N/A* (*not available*) in *Column 3*. Use a new row for each drug.
4. **Frequency**: For each drug purchased, write the number of times a day that the drug seller told you the dose was to be taken, for example, once a day, twice a day, three times a day, etc. If frequency is not mentioned, write *N/A* (*not available*) in *Column 4*. Use a new row for each drug.
5. **Duration of Treatment (days):** Write the number of days the purchased drug is to be taken for a full course of treatment. Write exactly what the drug seller says. The duration could be expressed as 3 days, 7 days, etc. If duration is not mentioned, write *N/A* (*not available*) in *Column 4*. Use a new row for each drug.
6. **How to take (administration):** For how to take the drug, write exactly what the drug seller says to the patient/caregiver. Administration can be expressed as after meals, with water, etc. If instructions are not mentioned by the drug seller, write *N/A* (*not available*) in *Column 5*.
7. **Price Paid:** For each drug sold by the drug seller, record the total price paid for the drug.

Simulated Client Form for Uncomplicated Diarrhea in

Name of ADDO: _____ **Location:** _____

Name of Simulated Client/data collector: _____ **Date of visit:** _____

1. For all drugs sold to the client, write the following information. (*Include ORS*)

Name	Strength	Dosage Form	Total Quantity	Dosage quantity	Frequency	Duration of Treatment *(days)*	How to Take	Price Paid
Col. 1			Col. 2	Col. 3	Col. 4	Col. 5	Col. 6	Col. 7
E.g. Imodium	2mg	Tab	2 tablets	2 tablets	once	1 day	with food	500

2. What drugs were recommended by the drug seller but not purchased?

a. _____   b. _____   c. _____

3. Did the drug seller ask about the symptoms of the child?   **Yes** ☐ **No** ☐

4. Did the drug seller ask about any other medicines the child may have taken?   **Yes** ☐ **No** ☐

5. Did the drug seller give instructions on how to take the medications?   **Yes** ☐ **No** ☐

6. Did the drug seller give information on how to look for danger signs?   **Yes** ☐ **No** ☐

7. Did the drug seller recommend immediate referral to a doctor or clinic?   **Yes** ☐ **No** ☐

8. Did the drug seller recommend referral to a doctor or clinic if danger signs arose   **Yes** ☐ **No** ☐

9. Did the drug seller recommend returning if symptoms did not get better?   **Yes** ☐ **No** ☐

Annex 5: Average Availability of Tracer Drugs in Singida and Mara

Tracer drug	Singida Pre # (%)	Singida Post # (%)	Mara Pre # (%)	Mara Post # (%)	Singida difference (percentage points)	Mara difference (percentage points)	Between-group difference (percentage points)	P-Value
Part I Drugs								
Amoxicillin 125mg/5ml susp	14(44)	22(76)	11(33)	17(53)	32	20	12	P=0.065
Amoxicillin 250mg caps	13(41)	27(93)	14(42)	15(48)	52	6	46	**P<0.05***
Artemether-lumefantrine 20/120 6 x 4 tabs	1(3)	2(7)	1(3)	0	4	−3	7	P=0.131
Benzyl penicillin 5MU injection	2(6)	6(21)	3(9)	6(19)	15	10	5	P=0.849
Chloroquine tablets	53(80)	1(2)	47(73)	13(32)	−78	−41	−37	**P<0.05***
Combined contraceptive pill	9(28)	17(59)	10(30)	21(67)	31	37	−7	P=0.815
Co-trimoxazole susp 200/40 mg	8(25)	27(93)	11(33)	17(52)	68	19	49	**P<0.05***
Co-trimoxazole tabs 400/80mg	13(41)	26(90)	14(42)	21(66)	49	24	25	**P<0.05***
Doxycycline tabs or caps 100mg	9(28)	20(69)	5(15)	10(31)	41	16	25	**p<0.05***
Erythromycin susp	8(25)	21(72)	8(33)	11(34)	47	1	46	**p<0.05***
Erythromycin tabs 250mg	10(31)	25(86)	11(33)	14(44)	55	11	44	**p<0.05***
Glucose infusion 5%	2(6)	3(10)	1(3)	2(6)	4	3	1	P=1.00
Ketoconazole 200mg tablets	2(6)	5(17)	2(6	7(21)	11	15	-4	P=0.649
Metronidazole susp	7(22)	14(48)	11(33)	17(53)	26	20	6	p=0.705
Metronidazole tabs 200mg	17(53)	25(86)	19(59)	22(69)	33	10	23	p=0.105
Nystatin pessaries 100,000 IU	1(3)	5(17)	1(3)	1(3)	14	0	14	P=0.982
Nystatin suspension 100,000 IU	4(13)	12(41)	4(12)	11(33)	28	21	7	P=0.573
Procaine penicillin Fortified 4MU	5(16)	15(52)	3(9)	4(12)	36	3	33	**P<0.05***

|								
Quinine injection	3(9)	4(14)	9(19)	7(22)	5	3	2	*p=0.412*
Sodium chloride infusion 0.9%	1(3)	1(3)	1(3)	0	0	−3	3	*NA[24]*
Sulfadoxine + pyrimethamine tabs	21(66)	24(83)	22(67)	25(79)	17	12	5	*p=0.649*
Sulfametopyrazine + pyrimethamine tabs	24(75)	19(66)	18(55)	28(88)	−9	33	−42	***p<0.05****
Sulphametopyrazine + pyrimethamine 525mg tablets	24(75)	20(69)	18(55)	28(88)	−6	33	−39	***P<0.05****
Tetracycline eye ointment 1% 3.5 g	14(44)	16(55)	8(18)	11(33)	11	15	−4	*P=0.102*
Part II Drugs								
Acetyl salicylic acid tablets 300mg	30(94)	22(76)	29(88)	27(85)	−18	−3	−15	*P=0.362*
Albendazole tabs 200mg	21(66)	23(79)	28(85)	24(75)	13	−10	23	*P=0.689*
Benzoic salicylic acid ointment	11(34)	17(59)	23(70)	17(52)	25	−18	43	***P<0.05****
Condoms	20(63)	25(86)	23(70)	20(61)	23	−9	32	***P<0.05****
Mebendazole 100mg tablets	17(53)	21(72)	25(76)	17(52)	19	−24	43	***P<0.05****
ORS	23(72)	24(83)	23(70)	22(70)	11	0	11	*p=0.204*
Paracetamol 500mg tablets	30(94)	28(97)	32(97)	32(100)	3	3	0	*P=0.290*
Zinc tablets 20mg	0	8(28)	3(9)	17(52)	28	43	−15	***p<0.05****

*Difference between regions was statistically significant.

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[24] Numbers too small to run statistical functions

Annex 6: Median Products Prices per Unit from Survey Compared with International Price Guide (TZS)

Trace Item	Baseline			Endline		
	Singida N=32	Mara N=33	2009 IPG	Singida N=29	Mara N=33	2010 IPG
Suspensions and Ointments						
Amoxicillin Susp 125mg	50	50	810	1500	1500	720
Benzyl Penicillin Inj 5MUS	1500	1500	513	1000	750	600
Cotrimoxazole Susp 240mg-5ml	800	700	634	2000	1500	465
Erythromycin Susp 125mg	1650	1500	1039	2000	1500	1380
Metronidazole Susp 200mg	1000	1200	878	1500	1500	765
Procaine Penicillin Fort 4MU	600	500	435	1000	900	274
Tetracycline eye oint 3.5g	500	500	395	700	500	461
Capsules/Tablets						
Amoxicillin Caps 250mg	50	50	30.2	70	50	31
Cotrimoxazole Tabs 480mg	50	22.5	15	50	25	16
Doxcycline caps 100mg	100	50	25	100	75	23
Erythromycin Tabs 250mg	100	50	46	100	60	64
Metronidazole Tabs 200mg	30	20	6.75	30	20	9
Antimalarials						
AL	700	100	263	633	100	89
Quinine injection	600	500	230	900	300	853
SP tabs 525mg	100	200	32	333	200	124
Sulfametopyr-pyrim tabs 525mg	500	500		500	500	
Antidiarrheal						
ORS	300	300	163	450	300	76
Zinc tabs 30mg	100	100	31	100	75	35
Others						
Albendazole	500	250	27	400	250	32
Aspirin	10	10	3	10	10	3
Benzoic salicylic acid oint	1000	800	259	1200	1000	330
Condoms	100	200		150	100	
Contraceptive pill	300	300		400	300	546
Glucose infusion 5%	1500	1500	675	2000	1500	750
Ketoconazole tablets 200mg	300	200	46	200	300	70
Mebendazole tablets 100mg	20	20	6	33	20	6
Nystatin pessaries 100,000iu	2000	1000	691	1500	2500	380
Nystatin susp 100,000iu	1750	1000	1526	2000	1500	1035
Paracetamol tabs 500mg	10	10	6	20	10	7
Sodium chloride 0.9%	1500	1500	810	1500	—	675

Health Facilities in Kibaale District

Health Facilities in Mpigi District
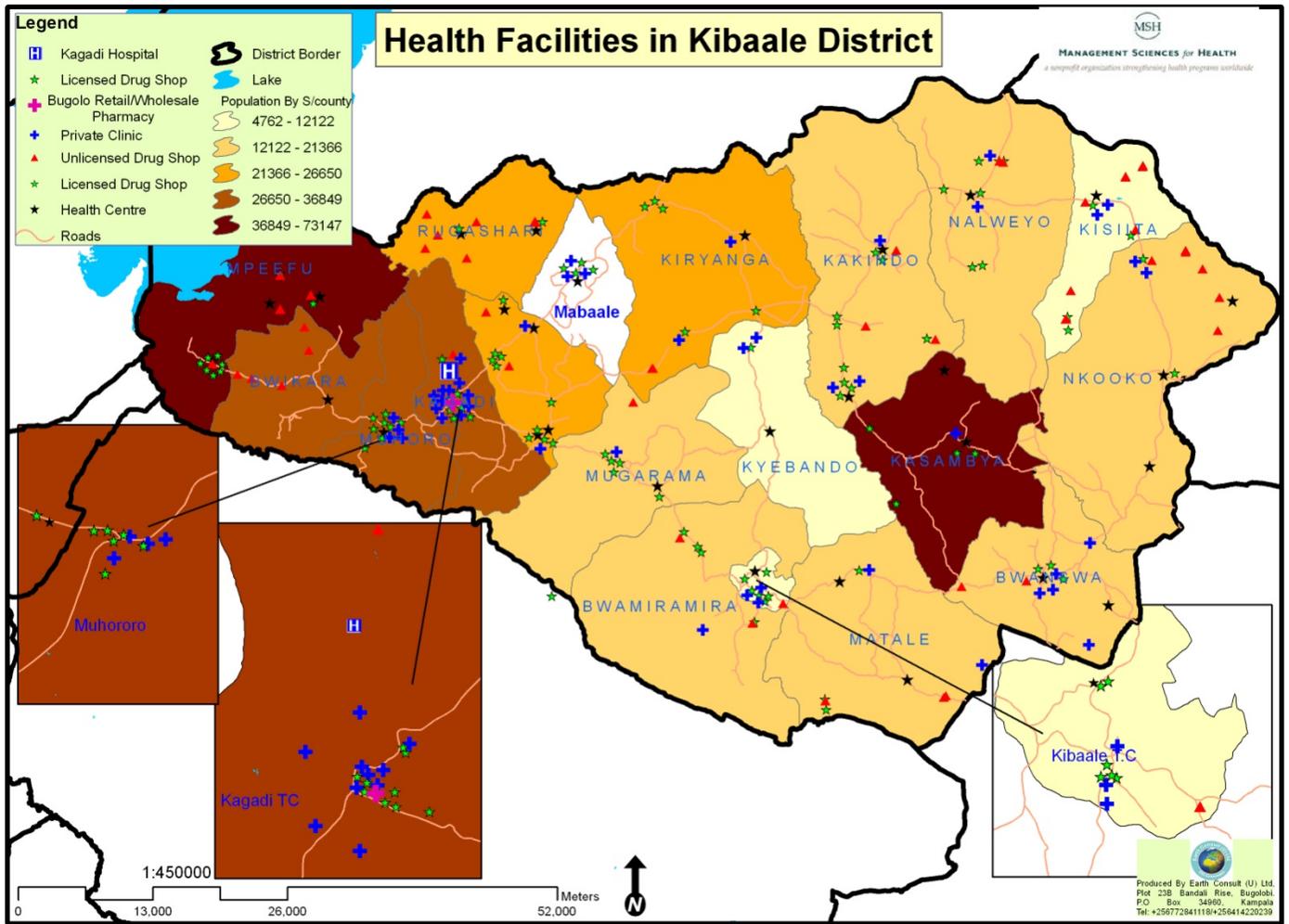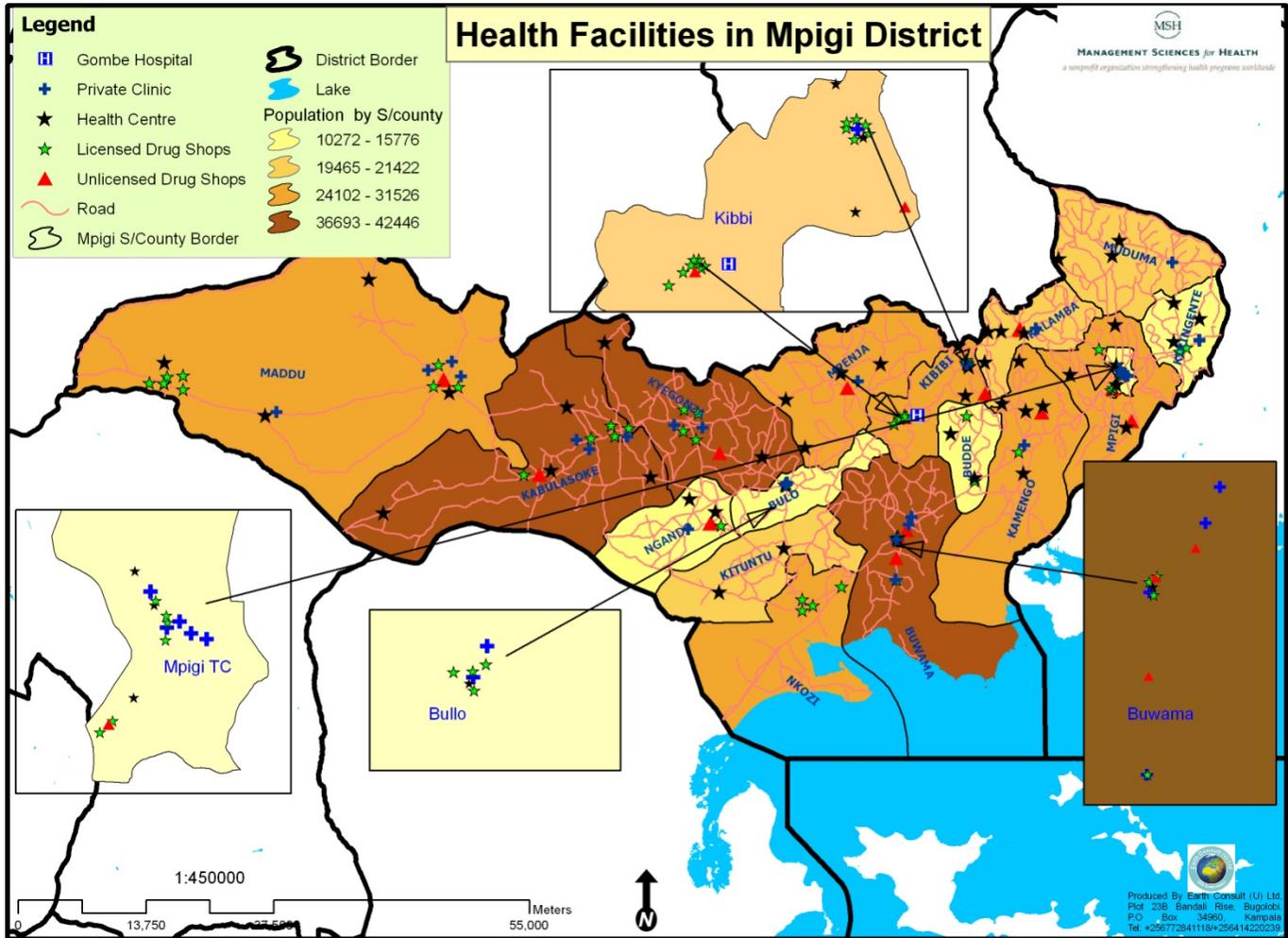
Annex 8: Average Availability of Tracer Drugs in Kibaale and Mpigi

Tracer drug	Kibaale Pre # (%)	Kibaale Post # (%)	Mpigi Pre # (%)	Mpigi Post # (%)	Kibaale difference (percentage points)	Mpigi difference (percentage points)	Between group difference (percentage points)	P-Value
Class B Drugs								
Amoxicillin 125mg/5ml susp	34(52)	40(89)	37(58)	26(63)	37	5	32	**P<0.05***
Amoxicillin 250mg caps	44(67)	42(93)	44(69)	26(63)	26	−6	32	**P<0.05***
Artemether-lumefantrine 20/120 6 x 4 tabs	3(5)	39(87)	6(6)	38(93)	82	87	−5	p=0.291
Benzoic salicylic acid ointment	14(21)	11(24)	20(31)	17(41)	3	10	−7	P=0.401
Benzyl penicillin 5MU injection	41(62)	0	19(30)	14(34)	−62	4	−58	**P<0.05***
Chloroquine tablets	53(80)	1(2)	47(73)	13(32)	−78	−41	−37	**P<0.05***
Combined contraceptive pill	37(56)	30(67)	48(75)	32(78)	11	3	8	P=0.240
Co-trimoxazole 480mg tabs	51(77)	42(93)	53(83)	31(76)	16	−7	23	**P<0.05***
Co-trimoxazole susp	45(68)	38(84)	37(58)	21(51)	16	−7	23	**P<0.05***
Doxycycline 100mg caps or tabs	28(42)	37(82)	39(61)	24(59)	40	−2	42	**p<0.05***
Erythromycin 250mg tabs	34(52)	36(80)	34(53)	22(54)	28	1	27	**p<0.05***
Erythromycin susp**	—	—	—	—	—	—	—	—
Glucose infusion 5%	20(30)	1(2)	18(28)	11(27)	−28	−1	−27	**P<0.05***
Ketoconazole 200mg tablets	5(8)	3(7)	10(16)	9(22)	−1	6	−7	**P<0.05***
Metronidazole 200mg tabs	38(58)	37(82)	51(80)	32(78)	24	−2	26	p=0.414
Metronidazole susp 200mg/5ml**	—	—	—	—	—	—	—	—
Nystatin pessaries 100,00 iu	21(32)	30(67)	24(38)	23(56)	35	18	17	**P<0.05***
Nystatin suspension 100,000 iu	14(21)	31(69)	14(22)	11(27)	27	5	22	**P<0.05***
Procaine penicillin Fortified 4MU	39(59)	0	25(39)	15(37)	−39	−2	−37	**P<0.05***
Quinine injection	39(59)	1(2)	26(41)	18(44)	−57	3	54	**p<0.05***
Sodium chloride Infusion 0.9%	18(27)	0	21(33)	14(34)	−27	1	−28	**P<0.05***
Sulfadoxine + pyrimethamine tabs	58(88)	3(7)	52(81)	35(85)	−81	4	−77	**p<0.05***
Sulfametopyrazine + pyrimethamine tabs	10(15)	0	17(27)	0	−15	0	15	p=0.523
Tetracycline eye	26(39)	29(64)	41(64)	34(83)	25	19	6	P=0.053

ointment 1% 3.5 g								
Class C Drugs								
Acetyl salicylic acid tablets 300mg	37(56)	17(38)	45(70)	31(76)	−18	6	−24	**P<0.05***
Albendazole 200mg tabs	18(27)	30(66)	30(47)	23(56)	39	9	30	**P<0.05***
Condoms	55(83)	36(80)	50(78)	39(95)	−3	17	−20	**P<0.05***
Mebendazole 100mg tablets	57(86)	40(89)	48(75)	30(73)	3	-2	5	P=0.061
ORS	33(50)	39(87)	50(78)	36(88)	37	10	27	p=0.576
Paracetamol 500mg tablets	66(100)	44(98)	60(94)	41(100)	−2	6	−7	P=0.314
Zinc tabs	6(6)	28(62)	8(13)	10(24)	56	11	45	**p<0.05***

*Difference between regions was statistically significant

**Data unavailable

Annex 9: Median Products Prices per Unit From Survey Compared with International Price Guide (UGX)						
	Baseline			Endline		
	Kibaale N=66	Mpigi N=64	2008 IPG (UGX)	Kibaale N=45	Mpigi N=41	2010 IPG (UGX)
Suspensions and Ointments						
Amoxicillin Susp 125mg	1650	2000	960	2000	2000	1140
Benzyl Penicillin Inj 5MUS	500	500	673	—	500	976
Cotrimoxazole Susp 240mg-5ml	1000	1500	624	1500	1500	736
Procaine Penicillin Fort 4MU	1000	1000	792	—	1000	433
Tetracycline eye oint 3.5g	500	600	268	800	1000	301
Capsules/Tablets						
Amoxicillin Caps 250mg	100	100	46	100	100	49
Cotrimoxazole Tabs 480mg	30	50	23	50	50	25
Doxcycline caps 100mg	100	100	31	100	100	36
Erythromycin Tabs 250mg	100	100	61	100	150	101
Metronidazole Tabs 200mg	25	50	8	25	50	14
Antimalarials						
ALU	354	312	312	292	250	140
Chloroquine	20	33	32	150	100	48
Quinine Injection	1000	1000	1446	1000	1000	1350
SP tabs 525mg	167	333	2262	500	500	196
Sulphametopyr-pyrim tabs 525mg	1500	1500	—	—	—	—
Antidiarrheal						
ORS	300	300	242	400	300	122
Zinc tabs 30mg	175.5	175	60	200	200	56
Other Medicines						
Albendazole	500	500	96	500	750	51
Aspirin	10	12.5	20	10	20	10
Benzoic-salicylic acid oint	1500	1500	198	1500	2000	333
Condoms	300	300	136	500	500	704
Contraceptive pill	300	300	—	500	500	—
Glucose infusion 5%	2000	2000	880	2000	2500	1188
Ibuprofen tablets 200mg	25	50	9	45	50	13
Ketoconazole tablets 200mg	500	800	133	300	500	111
Mebendazole tablets 100mg	20	45	10	27.5	50	10
Nystatin pessaries 100,000iu	200	200	115	200	250	43
Nystatin susp 100,000iu	2500	2500	1670	2500	2500	1639
Paracetamol tabs 500mg	12.5	20	9	20	25	12
Sodium Chloride 0.9%	2000	2000	1120	—	2500	1069